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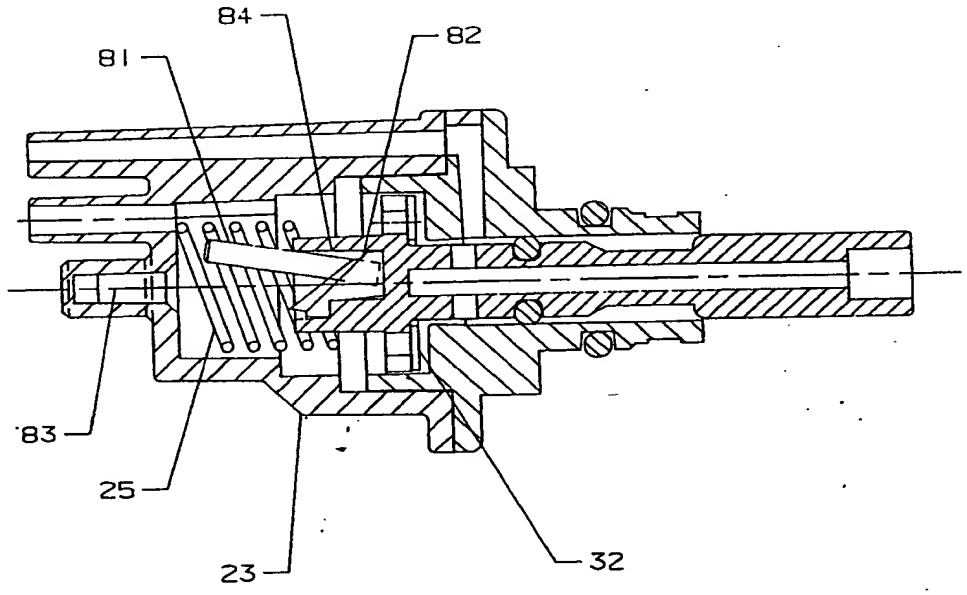

(57) Abstract

An improved connector assembly, with an internal shut-off valve, which may reliably and easily be inserted into and removed one-time from either of both types of endoscope mount designs, provides increased patient safety, cost-effectiveness, single-use, sterility. It features means defining a first channel (9, 10, 11, 29), for transfer of liquid from said container (8) to said endoscope (1), means defining a second channel (5, 6, 28), for transfer of gas into said container (8) in order to displace said liquid, valve means (21, 26), adjustable between at least a channel-opening first position (Fig. 3C) and a channel-closing second position (Fig. 3D), for gating said first and second channels (29, 28), and means (25, 22, 30), responsive to disconnection of said endoscope, for irreversibly setting said valve means to said channel-closing second position (Fig. 3D). The setting means may include a metal pin (81) which becomes dislodged from a recess (83) and, due to lateral loading exerted by an elastomeric grommet (82), will not go back into the recess.

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ENDOSCOPE STERILE LIQUID SUPPLY SYSTEM

FIELD OF THE INVENTION:

The present invention relates generally to systems for delivering uncontaminated fluids, particularly sterile fluids, to medical instruments used on the human body, for example to clean off lenses of scopes. The invention could also be adapted for use in handling non-germ-related types of contamination.

BACKGROUND: An endoscope is a medical instrument which is inserted into the body to visualize the interior of a body cavity or hollow organ, for example to check for signs of cancer or other abnormalities. It is common medical practice to deliver water via an endoscope channel to clear the endoscope lens for better visualization of the field. Medical personnel conventionally utilize a reusable, sterilizable water bottle with a cap and a tubing set that connects to the endoscope. Fluid delivery is activated by pressurizing the water bottle with air delivered from a channel in the endoscope through one tube in the tubing set. Water is forced out of the bottle through a second tube in the tubing set and into a second channel in the endoscope to the lens.

The Society of Gastroenterology Nurses and Associates (SGNA) has issued Guidelines for Infection Control. The current Guidelines recommend that the water bottle and tubing be sterilized daily. When performing any type of Endoscopic Retrograde Cholangio-Pancreatography (ERCP) procedure, a sterile bottle and tubing set are recommended for use in every case. In all instances, sterile water should be used in the bottle.

The American Society for Gastrointestinal Endoscopy (ASGE), American Gastroenterological Association (AGA), and American College of Gastroenterology (ACG) guidelines are less specific with regard to sterilization. They simply state that "the water bottle needs to be disinfected on a regular basis". In cases of immunosuppressed patients, however, they recommend that the water bottle used be sterilized or disinfected prior to the procedure and sterile water be used during the procedure.

The U.S. government's Center for Disease Control (CDC) does not specifically mention water bottles, but does state that laparoscopes, arthroscopes, and other scopes that enter normally sterile tissue should be sterilized before each use, or receive high-level disinfection if sterilization is not feasible. Flexible endoscopes should receive high-level disinfection.

The Association for Practitioners of Infection Control (APIC) recommends the same guidelines as the CDC with the addition of a sterile water rinse to follow the high-level disinfections. They do not mention water bottles, but state that other accessories, such as suction valves, should be sterilized or at least high-level disinfected after every use.

If the reusable water bottle, cap and tubing set is not sterilized or disinfected as recommended, it becomes a source of contamination to the patient. Patient safety is compromised. Methods of sterilizing or disinfecting the device include cold sterilization (liquid), gas sterilization, steam sterilization and alcohol rinse. These procedures are currently performed by medical personnel at different frequencies, ranging from once at the end of the week, to once at the end of the day (most common practice), to once at the end of each procedure. All of the procedures require the time of medical personnel, space, equipment and expendables. All of these procedures require the refilling of the water bottle with sterile water.

Conventional cap and tubing sets are composed of a water bottle, cap, two (2) pieces of tubing and an endoscope connector. Three (3) types of endoscope mounts exist (Types A, B and C) and three (3) types of connectors exist to interface properly (Types A, B, and C, respectively). The water bottle, cap and tubing are made of autoclavable polymeric materials. The endoscope connectors are made of expensive, high precision machined, metal components, O-rings, and (in Type B only) a spring. Type A and C endoscopes are sold under the trademarks OLYMPUS and PENTAX, among others. Type B endoscopes are sold under the trademark FUJINON, among others. The Type C mount is similar to the Type A mount. The Type C mount is typical of OLYMPUS video scopes. The primary difference between Types A and C and Type B endoscope mounts is the interface design.

The Type A connector is inserted into the Type A endoscope mount. The air and water seals required for pressurizing the bottle and transferring liquid with the Type A interface are maintained via O-rings. The O-ring on the connector provides the endoscope air-to-room air seal. The O-ring on the endoscope mount provides the endoscope air-to-water seal.

Type B connector is mounted flush to the Type B endoscope mount. The endoscope air-to-room air and the endoscope air-to-water seals are provided by a spring force on the metal connector onto a rubber gasket on the endoscope mount. The type B connector also provides a shut-off valve that prevents water from passing through the connector when, after use, it is no longer mounted on the endoscope.

The major limitation of the current state-of-the-art devices is their inability to ensure patient safety and to do so cost-effectively. Surveys of medical personnel indicate that the recommended procedures for sterilizing and cleaning are <u>not</u> being followed. Cost and availability of medical personnel time are prohibitive with the current state-of-the-art devices.

The cost of the current state-of-the-art device prohibits its use as a disposable. A method of making such a device single-use is currently not available.

As a result of the current state-of-the-art limitations of endoscope lens cleaning water delivery devices, a clear need exists to provide the medical community with a fail-safe, cost-effective system which may be reliably utilized and which may reliably not be re-utilized after a single use. The invention set forth below intrinsically fulfills this need.

THE INVENTION:

It is among the objects of the present invention to increase patient safety by reducing the possibility of cross-contamination, or contamination by air-borne bacteria and viruses, and resulting infection, lower the total cost of the system components and utilization requirements, reduce the time required to prepare the system for use on a patient and ensure the device is single-use, while maintaining the functions of the current state-of-the-art systems.

Briefly, the present invention replaces the conventional, reusable, water delivery system with a single-use disposable device which, except for a spring and stainless steel pin, is composed entirely of polymeric material. The water bottle is a pre-filled container with sterile water for irrigation. The sterilized connector assembly consists of a bottle cap, dual tubing, a connector which interfaces with a Type A or Type C endoscope and an adapter which adapts the connector to fit Type B endoscopes.

In the preferred embodiment, pushing the connector into engagement with the endoscope opens or creates a water channel, a gas channel, or both, and stores energy by compressing a spring. After use on a first patient, when the endoscope is disconnected for sterilization, the stored energy is released and used to close one or both channels.

This prevents re-use of the connector for a subsequent patient. Thus, the subsequent patient cannot be exposed to germs from the first patient, which might be left in the connector system.

In order to use the system, a tamper-evident seal on the pre-filled sterile water container is removed, the connector assembly cap is screwed on tightly, to assure the air pressure seal required, and the connector, with adapter if required, is connected to the endoscope.

A special feature is that the cap can be screwed onto the bottle but is not removable, making the bottle non-refillable. Internal components of the connector, whether used with or without the adapter, permanently close the water path after a single use, making it non-reusable. The present invention provides enhanced safety due to its single-use design. Safety will also be improved by the reduction in potential operator error, for example, not rinsing the current device properly after cold sterilization. Safety will also be improved by eliminating the prior art requirement to transfer water; this transfer sometimes introduces pathogens (germs).

All components are designed for ease of manufacturing, assembly and sterilization, to make the device a cost-effective disposable for the medical community. The cap, connector and adapter are preferably composed of all injection-molded components (except for a gasket, two O-rings, a bushing, a stainless steel pin, and a spring or living hinge, also possibly plastic) which are easily press-fit, sonic-welded or solvent-bonded together. Tubing is made of inexpensive, radiation-compatible material which is easily solvent-bonded.

These features of the present invention fulfill well-recognized needs in the medical community for a safe, easy-to-use endoscope water delivery system. These advantages will be further apparent from the following detailed description

and the accompanying drawings. The following description of the preferred embodiment specifically relates to an endoscope water delivery system for lens cleaning; however, the invention may also easily be adapted for delivery of water for other purposes and for delivery of other fluids, such as contrast material used in X-ray or other imaging procedures, through the endoscope channels.

DRAWINGS: These and other advantages of the present invention will be apparent from the drawings, in which:

Fig. 1 is a schematic view of a delivery system, showing the pre-filled water container, the cap, the dual tubing leading therefrom, the connector, the adapter, the endoscope interface and the light and air supply unit interface;

Fig. 2 is a side view cross-section of the cap, showing its three-piece assembly and mounting arm;

Fig. 2A is an end view of the inside of the outer cap element and Fig. 2B is an end view of the outside of the inner cap element;

Fig. 3A is a cross-sectional exploded view of the nine components of the connector in its preferred embodiment;

Fig. 3B is a cross-sectional view of the connector of Fig. 3A, as shipped to a user (the "shipped" state);

Fig. 3C is a cross-sectional view of the connector during use, after connection to an endoscope (the "open" state);

Fig. 3D is a cross-sectional view of the connector after use with a patient, and disconnection from the endoscope (the "closed" state), showing an internal pin dislodged;

Figure 4 is a cross-sectional view of an adapter on the connector in the open state;

Fig. 4A shows a two-step cam for connection to an adapter;

Fig. 5 is a cross-sectional view of an alternate adapter;

Fig. 6 is a cross-sectional view of an alternate connector;

Fig. 7 is a cross-sectional view of an alternate connector;

Fig. 8 is a cross-sectional view of an alternate connector;

Fig. 9 is a cross-sectional view of an alternate connector;

Fig. 10 is a cross-sectional view of an alternate connector and adapter:

Fig. 11 illustrates an OLYMPUS-type endoscope mount;

Fig. 12 shows a FUJINON endoscope mount;

Fig. 13 shows the connector of Fig. 3D with an element which, when fully extended, prevents engagement of the connector with the endoscope mount of Fig. 11;

Fig. 14 shows the connector of Fig. 3D with an element which, when fully extended, prevents engagement of the connector with the endoscope mount of Fig. 12;

Figs. 15A, 15B, and 15C illustrate, respectively, the "before use", "in use" and "after use" states of an alternative embodiment incorporating a "living hinge" of memory plastic;

Figs. 16A, 16B and 16C illustrate, respectively, the "before use", "in use" and "after use" states of an alternative embodiment incorporating multiple ramps to prevent return movement of the piston;

Fig. 17 illustrates an alternate embodiment of the cap using a welded or molded ring instead of the undercut shown in Fig. 2.

DETAILED DESCRIPTION:

Fig. 1 illustrates the overall delivery system of the parent invention. An endoscope 1 is connected to a light and air supply unit 2. Activation of a depressor valve 3 on the endoscope 1 by the operator allows air to pass from the light- and air-supply unit 2 to the connector 4 and into the air tube 5, through the air port 6 on the cap 7 and into the pre-filled sterile water container or bottle 8. Air pressurizes the pre-filled, sterile water container 8, forcing water out through the "down" tube 9, through water port 10 of cap 7, through the water tube 11, through the connector 4 and into the endoscope 1 to the patient. When the depressor valve 3 is released, the air path is cut off and water stops flowing. A mounting arm 12 is provided, to enable mounting the pre-filled sterile water container onto the light- and air-supply unit 2.

Fig. 2 is a cross-sectional view of cap 7. The cap 7 includes an outer member 13 having circular hole 14 on top, angled steps on inner surface 16, and a mounting arm 12. An undercut 15 (as shown in Fig. 2) or a welded or bonded ring 15 (as shown in Fig. 17) locks the cap inner member 17 in place and the circular hole 14 provides an opening for the air port 6 and water port 10 to pass through. Alternately, an undercut could be formed on outer cap 13 to facilitate press fit insertion of inner member 17, with retention sufficient to discourage disassembly by the user. The mounting arm 12 is to enable mounting the pre-filled sterile water container 8 onto the light and air supply unit 2, which typically has a loop into which arm or hook 12 slides vertically.

As shown in Figs. 2A and 2B, the inner member 17 of cap 7 has grooves 18, which lock together with angled steps 16 of outer cap member 13 during clockwise rotation of the cap onto the bottle 8, as viewed from the open end of the bottle.

During any attempted counter-clockwise rotation of cap 7, the angled steps 16 do not interlock with the grooves 17. The cap therefore will not come off the bottle, so it becomes impossible to re-use the cap-and-tubing set on a new water bottle for a subsequent patient, which might contaminate the subsequent patient. Right-hand threads 19 are provided to interface with the threads on the pre-filled sterile water container 8. Gasket 20 is seated inside cap inner member 17 to form an airtight seal between the inner cap member 17 and the pre-filled sterile water bottle or container 8.

As shown in the exploded view of Fig. 3A, except for two rubber or rubber-like O-rings 26 and 34, a spring 25, a gasket 86, a rubber or rubber-like bushing 82, and a stainless steel pin 81, connector 4 preferably comprises only three elements: a piston 21, a hose junction 23 and an insert base 24.

A suitable material of piston 21 is polypropylene. Hose junction 23 and insert base 24 may comprise, for example, ABS (Acrylonitrile-Butadiene-Styrene), and may be solvent-bonded together using a solvent such as methylene chloride or alternately sonically welded together.

Pin 81 preferably comprises type 303 stainless steel. Pin 81, having a serrated surface to provide an interference fit, is inserted into the bushing 82. The serration may take the form of longitudinal fins and grooves spaced 120° apart around the circumference of pin 81. Pin 81 is preferably about 0.44 inches or about 1.12 cm long. The end inserted into bushing 82 is preferably about 0.066 inches or 1.68 mm in diameter, with the remaining length of the pin slightly smaller. The bushing-remote end of pin 81 preferably has an approximately diagonal chamfer to facilitate insertion in a cylindrical recess or core 83, shown in Fig. 3D, in hose junction 23. That recess or core preferably has a diameter of about 0.086 inches or about 2.18 mm.

Bushing or grommet 82 preferably comprises a thermoplastic elastomer such as that sold by Monsanto Co. of St. Louis, Missouri, USA under the trademark SANTOPRENE (U.S. Reg. No. 1,081,414). Bushing 82 is molded with a blind hole, to prevent the pin from being pushed through. The hole preferably has a diameter of the about 0.050 inches or 1.27 mm and a depth of about 0.070 inches or about 1.78 mm; thus, the bushing must distend somewhat to receive pin 81. To reinforce the bottom of the hole, the exterior surface of the bushing remote from the hole may be formed with a button about 0.080 inches or about 2 mm in diameter and about 0.02 inches or about .5 mm in height.

Figs. 3B-3D and 16 are cross-sectional views of two different embodiments of the connector 4 in the shipped (before use), open (in-use), and closed (after use) states. In the Fig. 16 shipped state, piston 21 is locked in place by tabs 22 between the base 23 and the insert 24. The tabs 22 are connected to the piston 21, preferably molded as one piece. As shown, there is only a thin bridge of material connecting each tab 22 to the rest of piston 21. The piston 21 holds the spring 25 in partial compression.

When the connector 4 is manually inserted toward the right of Fig. 3B into the endoscope, the piston 21 is forced into the hose junction 23 (see Fig. 3C), and the bridges supporting tabs 22 are sheared off. This action compresses the spring 25. O-ring 26 seals up against O-ring groove 27, making a seal between the air channel 28 and the water channel 29. The action also pushes pin 81 and bushing 82 into a seat 64 in piston 21, causing the bushing to become eccentrically compressed with respect to the center line or longitudinal axis of piston 21, thereby resulting in a lateral load applied to pin 81.

The O-ring 34 provides two functions: a seal is maintained between the connector and endoscope air channels, and the O-ring retains the connector in the endoscope fitting.

When the connector 4 is removed from the endoscope, the spring 25 (which is under compression) releases its stored energy to move the piston into the "after use" state, shown in Fig. 3D. As a result of the piston movement, bushing 82 and pin 81 are also pulled toward the distal end of the connector, resulting in the release of pin 81 from a core or recess 83 formed in hose junction 23.

Because of the lateral load previously applied by the eccentric compression of bushing 82, pin 81, once released, moves to the angled position shown in Fig. 3D, which is at a diagonal with respect to the seat 64, shown in Fig. 3A, on piston 21. The angled orientation of pin 81 prevents piston 21 from being repositioned into the "in-use" position of Fig. 3C, thereby preventing reuse of the sterile liquid supply system. A piston disc forces a gasket up against a shutoff surface 32 by the compression still remaining in spring 25, preventing the flow of water through the water gates.

O-ring 34 comes into contact either directly with an OLYMPUS-type endoscope mount (shown in Fig. 11) or with an adapter 35 (shown in Fig. 4) for a FUJINON endoscope mount and provides a seal between the connector and the endoscope air channels. Adapter 35 connects to FUJINON endoscope mount 164 (Fig. 12).

The water channel seal between connector and endoscope can be created, in the case of an OLYMPUS-type endoscope, using an an O-ring Fig. 11 or, in the case of a FUJINON endoscope, using a resilient gasket as shown in Fig. 12.

According to an embodiment shown in Figs. 16A-16C, when the connector 4 is removed from the endoscope, the spring 25 (which is under compression) tries to move to a relaxed position, forcing piston 21 to move past lock tabs or ramps 30. The piston disc 31 is forced up against the shutoff surface 32 by the compression still remaining in spring 25, preventing the flow of water through the water gates 33.

Fig. 4 is a cross-sectional view of an adapter 35 locked onto the connector 4 in the open (during use) state. Adapter 35 permits use, with Type B endoscopes (for example FUJINON), of the same connector 4 used for Type A endoscopes.

The adapter 35 is locked to the connector 4 via lock ring 36 which snaps-fits into the lock channel 37. Compatibility of adapter 35 with a variety of Type B endoscopes is assured through the implementation of a two-step cam lock 86, as illustrated schematically in Fig. 4A.

Channel 37 is formed on the outer surface of a tapered cylindrical end of insert 24, which has a slot supporting the inside of O-ring seal 34. Adapter 35 is formed with a correspondingly tapered end which slips over the end of insert 24 and engages outer surface of O-ring seal 34. The air-to-water seal is provided by forcing the piston 21 up against a rubber gasket on the endoscope mount via spring 25. The air-air seal is provided by holding the adapter 35 surface 38 against the endoscope mount rubber gasket via the bayonette locking mechanism grooves 39 which lock with pins on the endoscope mount.

Fig. 5 shows a cross-sectional view of an alternate adapter 35 to connector 4 lock mechanism. Lock arm or hook 40 is locked into lock channel or groove 41.

Fig. 6 shows a cross-sectional view of an alternate connector. Instead of using a piston disc 31 for closing the water gates 33, a shut-off ring 42 which is part of the alternate connector insert 43 shuts off the water by sealing against the alternate design piston cap 44.

Fig. 7 shows a cross-sectional view of an alternate connector design to accomplish water shut-off and non-reusability, it would be attached to the basic insert 24. During removal of the connector, sleeve 45 moves prior to the tube housing 46. This movement causes deflection of pinch tab 47 which pinches closed water tube 11. Sleeve 45 is locked into the pinched position by lock tab 48 snapping into lock channel 49.

Fig. 8 shows, in cross-sectional view, an alternate connector design to accomplish water shut-off and non-reusability. The water tube 11 passes through channel 50 and connected to channel 51. When connector is removed from endoscope sleeve 52 moves prior to tube housing 53. The movement of sleeve 52 is controlled by a cam action slot 54, resulting in a two-directional movement (away from the scope and rotation). The movement away from the scope causes walls 55 and 56 to pinch closed the tubing. The rotational movement enables this mechanism to be utilized with the adapter type endoscope mount as well. A locking mechanism similar to others previously described would be utilized.

Fig. 9 shows a cross-sectional view of an alternate connector design to accomplish shut-off of the water and non-reusability. When the connector is removed from the endoscope, pull tabs 57 force pressure points 58 through tear tabs 59 breaking the air channel 60 wall, preventing pressurization required for water delivery. The pressure points continue to move into the channel, pinching closed the water tube 11 which passes through the air channel 60 and connect to the water channel 61. Pull tabs 57 would lock into place.

Fig. 10 shows a cross-sectional view of an alternate connector design concept which does not provide water shut-off but relies on the non-removable cap design (Fig. 2) for non-reusability. The design simplifies the manufacturability of the current state-of-the-art by injection molding parts and assembling them.

Fig. 11 is a cross-sectional view of the mount portion of a typical prior art endoscope 63 such as those sold under the mark OLYMPUS. The mount defines a tubular cavity of stepped diameter which serves to receive element 21. A cylindrical projection into the cavity has a central bore to define water channel 29 and supports an O-ring running circumferentially around its outer surface. The O-ring serves to provide a seal for air channel 28.

Fig. 12 is a cross-sectional view of the mount portion of a typical prior art endoscope 64 such as those sold under the mark FUJINON. Instead of an O-ring, the function of channel sealing is performed by a resilient gasket within the cylindrical cavity defined by the endoscope mount. Water channel 29 is defined by a central bore, as in the Fig. 11 endoscope.

Fig. 13 illustrates the fact that piston element 21 can be so dimensioned that, when spring 25 fully extends element 21, the end of element 21 abuts the cylindrical projection within OLYMPUS endoscope mount 63 and prevents the remainder of the connector from sliding far enough into the endoscope mount to form a seal. Thus, once the connector and bottle assembly has once been used, spring 25 and locktabs 30 keep element 21 fully extended, and thus prevent re-mounting of the connector and bottle assembly on the OLYMPUS endoscope. The bottle and connector thus cannot be improperly re-used for a second patient.

Fig. 14 illustrates how full extension of element 21 prevents the FUJINON endoscope mount from coming close enough to engage adapter 35, similarly preventing improper re-use.

Figs. 15A, 15B and 15C illustrate, respectively, the "before use", "in use" and "after use" states of an alternative embodiment incorporating a "living hinge" of memory plastic. This embodiment uses a plurality of prongs 65 integrally molded to piston 21 in a fork configuration. This design relies upon the elastic memory, of the plastic material preferably used for the piston, to effect the spread of the fork upon transition of the connector from the "in-use" to "after-use" position. Once the prongs return to their "as molded" configuration, they cannot fit back into core 83 on hose junction 23. This assures that the connector cannot be re-used.

Figs. 16A, 16B and 16C show cross-sectional views of an alternate connector design concept to accomplish shut-off of water and non-reusability. This design utilizes multiple ramps or ratchets 30 integrally molded to insert 24 to provide relatively free movement of piston 21 toward the distal end (shown at right of each figure) of the connector and, after piston 21 passes ramps 30, a substantial detent against movement in the reverse direction (toward the left of the figure).

Various changes and modifications are possible within the scope of the inventive concept, and features of any of the disclosed embodiments could be combined with features of any of the others. Instead of using a spring 25 to store energy upon connection of the connector and endoscope, one could use another "living hinge" mechanism.

Instead of disabling the air/liquid channels upon disconnection of the connector assembly from the scope, one could provide means, responsive to a first connection of the endoscope to the connector assembly, for recognizing an attempted second connection of the endoscope to the connector assembly, and for thereafter disabling the endoscope seal or flow through at least one of the first and second channels.

NO.	PART	FIG.	
1	ENDOSCOPE		
2	LIGHT+AIR SUPPLY UNIT	1	
3	ACTUATOR VALVE	1	
4	CONNECTOR	1	
5	AIR TUBE	1	
6	AIR PORT ON CAP	1	
7	CAP OF BOTTLE	1	
8	WATER CONTAINER	1	
9	DOWN TUBE	1	
10	WATER PORT	1	
11	WATER TUBE FR. BOTTLE	1	
12	MOUNTING ARM	1	
13	OUTER CAP MEMBER	2	
14	CIRCULAR HOLE ON CAP	2	
15	WELDED RING	2	(REVISED)
16	INNER CAP SURFACE	2	
17	CAP INNER MEMBER	2	
18	GROOVES 18 OF 17	2	
19	RIGHTHAND CAP THREADS	2	
20	GASKET INSIDE CAP	2	
21	PISTON	3	
22	TABS	3	
23	BASE	3	
24	INSERT	3	
25	SPRING	3	
26	O-RING BET. 21 & 24	3	
27	GROOVE FORMED ON 24	3	
28	AIR CHANNEL 28	3	
29	WATER CHANNEL 29	3	
30	LOCK TABS	3	
31	PISTON DISC	3	
32	SHUT-OFF SURFACE	3	

NO.	PART	FIG.
33	WATER GATES	3
34	O-RING BETW. 4 & END.	3
35	ADAPTER	4
36	LOCK RING	4
37	LOCK CHANNEL	4
38	AIR SURFACE	4
39	LOCK ARM	5
40	HOOK	
41	LOCK CHANNEL	5
42	SHUT-OFF RING	6
43	ALT. CONN. BASE	6
44	PISTON CAP	6
45	SLEEVE	7
46	TUBE HOUSING	7
47	PINCH TAB	7
48	LOCK TAB	7
49	LOCK CHANNEL	7
50	CHANNEL	8
51	CHANNEL	8
52	END. SLEEVE	8
53	TUBE HOUSING	8
54	CAM ACTION SLOT	8
55	WALL	8
56	WALL	8
57	PULL TABS	9
58	PRESSURE POINTS	9
59	TEAR TABS	9
60	AIR CHANNEL	9
61	WATER CHANNEL	9
62	O-RING	10
63	ENDOSCOPE	11
164	MOUNT'S RECEIVING GROOVE FOR O-RING 62	12
66	LATCHING ELEMENT	

NO.	PART	FIG.
81	STEEL PIN	3A (REVISED)
82	BUSHING OR GROMMET	3A, 3B, 3D (REVISED)
83	CORE OR RECESS IN 23	3C (REVISED)
64	SEAT ON PISTON 21	3A, 3B, 3D (REVISED)
65	PRONGS OF PL. HINGE	15A, 15B, 15C
86	TWO-STEP CAM	

CLAIMS:

1. In a system for supplying a liquid to an endoscope (1) which is disconnected and sterilized after use with each patient being observed through said endoscope,

single-use connection means (4-12) for interconnecting a first container (8) of said liquid and said endoscope during use with a first patient and for blocking subsequent re-connection of said first container (8) with an endoscope (1) upon any attempted use with any subsequent patient, thereby preventing contamination of said subsequent patient by germs from said first patient,

comprising

means defining a first channel (9, 10, 11, 29), for transfer of liquid from said container (8) to said endoscope (1),

means defining a second channel (5, 6, 28), for transfer of gas into said container (8) in order to displace said liquid,

valve means (21, 26), adjustable between at least a first position (Fig. 3C) in which each of said channels is continuous and a second position (Fig. 3D) in which at least one of said channels is interrupted intermediate said container and said endoscope;

and

means (25, 22, 30), responsive to disconnection from said endoscope, for irreversibly setting said valve means to said second position (Fig. 3D).

2. The connection means of claim 1, wherein (Figs. 3A-3D) said valve means includes

a hose junction (23) and an base insert element (24) secured together,

a piston (21), slidable within said base and insert elements, and supporting an O-ring (26) mounted around said piston, forming a seal separating said first and second channels, and

a pin (81) and bushing (82) press-fitted together and fitted to said piston (21).

3. The connection means of claim 2, wherein (Figs. 16A-16C) said piston is formed with tabs (22) which break off upon mounting of said connection means on an endoscope,

said setting means includes a spring (25) which stores energy during mounting of said connection means on an endoscope, and

said setting means includes ramp interlock or ratchet means (30) formed on at least one of said piston (21) and said base insert element (24), for detaining said piston in said second position after release of energy from said spring (25).

4. The connection means of claim 2, wherein said piston is formed with a seat (64) which compresses said bushing (82) upon mounting of said connection means on an endoscope,

said hose junction is formed with a pin-receiving recess (83) which, in an initial state, receives said pin (81),

said setting means includes a spring (25) which stores energy during mounting of said connection means on an endoscope, and

said setting means includes means for preventing re-insertion of said pin (81) into said core or recess (83) after release of energy from said spring (25).

5. The connection means of claim 1, wherein (Fig. 4) said channel-defining means (23, 24) includes means for supporting a seal (34) for engagement with an endoscope, and further comprising

adapter means (35), including a first end interfitting with said seal-supporting means and a second end defining bayonette locking means (39) for locking said adapter means to said endoscope.

6. The connection means of claim 1, wherein (Fig. 5) said channel-defining means (23, 24) includes means for supporting a seal (34) for engagement with an endoscope, and further comprising

adapter means (35) including a first end interfitting with said seal-supporting means and a second end defining hook (40) and groove (41) means for locking said adapter means to said endoscope.

7. The connection means of claim 2, wherein (Fig. 6) said channel-defining means (23, 24) includes means for supporting a seal (34) for engagement with an endoscope, and further comprising a shut-off ring (42) formed as a part of said insert element (24), said ring acting to shut off said first liquid channel (29) by sealing against a piston cap (44).

8. The connection means of claim 1, wherein (Fig. 7) said channel-defining means (23, 24) includes means for supporting a seal (34) for engagement with an endoscope, and further comprising a sleeve (45) which moves prior to a tube housing (46), said movement causing deflection of a pinch tab (47) which pinches closed said first liquid channel (11), and a lock tab (48) which snaps into a lock channel (49).

9. The connection means of claim 1, further comprising (Fig. 8) a liquid water tube (11) passing through a first channel (50) and connected to a second channel (51); a sleeve (52) which, upon removal of said connection means from said endoscope, moves prior to a tube housing (53), at least one of said sleeve and said housing being formed with an essentially spirally aligned cam action slot (54), controlling relative movement thereof, movement away from said endoscope causing pinching closed of said liquid channel.

10. The connection means of claim 1, further comprising (Fig. 9) pull tabs or levers (57) formed on said channel-defining means, and including pressure points (58); and frangible wall elements (59) in said channel defining means, said levers (57) being pivotable to apply said pressure points to said frangible elements to thereby pierce the same and prevent maintenance of pressure in said gas channel, thereby disabling flow through said channels.

11. A system for supplying a liquid to an endoscope (1) which is disconnected and sterilized after use with each patient being observed through said endoscope, comprising

a bottle (8) adapted to hold a liquid and formed with an opening bearing a set of spiral threads;

and

a bottle cap (7) (Figs. 2, 2A, 2B) formed with two elements (16, 18) which interengage for common rotation in a first rotational direction for screwing said cap onto said spiral threads but fail to interengage upon attempted rotation in a second, opposite, rotational direction, thereby making said cap non-removable from said bottle.

12. In a system for supplying a liquid to an endoscope (1) which is disconnected and sterilized after use with each patient being observed through said endoscope,

single-use connection means (4-12) for interconnecting a first container (8) of said liquid and said endoscope during use with a first patient and for blocking subsequent re-connection of said first container (8) with an endoscope (1) upon any attempted use with any subsequent patient, thereby preventing contamination of said subsequent patient by germs from said first patient,

comprising

means defining a first channel (9, 10, 11, 29), for transfer of liquid from said container (8) to said endoscope (1),

means defining a second channel (5, 6, 28), for transfer of gas into said container (8) in order to displace said liquid,

and

means, responsive to disconnection of said endoscope from said connection means (4-12), for disabling flow through at least one of said first and second channels.

13. In a system for supplying a liquid to an endoscope (1) which is disconnected and sterilized after use with each patient being observed through said endoscope,

single-use connection means (4-12) for interconnecting a first container (8) of said liquid and said endoscope during use with a first patient and for blocking subsequent re-connection of said first container (8) with an endoscope (1) upon any attempted use with any subsequent patient, thereby preventing contamination of said subsequent patient by germs from said first patient,

comprising

means defining a first channel (9, 10, 11, 29), for transfer of liquid from said container (8) to said endoscope (1),

means defining a second channel (5, 6, 28), for transfer of gas into said container (8) in order to displace said liquid,

and

means, responsive to a first connection of said endoscope to said connection means (4-12), for recognizing an attempted second connection of said endoscope to said connection means and for thereafter disabling flow through at least one of said first and second channels.

14. In a system for supplying a liquid to an endoscope (1) which is disconnected and sterilized after use with each patient being observed through said endoscope,

single-use connection means (4-12) for interconnecting a first container (8) of said liquid and said endoscope during use with a first patient and for blocking subsequent re-connection of said first container (8) with an endoscope (1) upon any attempted use with any subsequent patient, thereby preventing contamination of said subsequent patient by germs from said first patient,

comprising (Figs. 11-14)

means defining a first channel (9, 10, 11, 29), for transfer of liquid from said container (8) to said endoscope (1),

means defining a second channel (5, 6, 28), for transfer of gas into said container (8) in order to displace said liquid,

an adjustable element (21, 26), adjustable between a first position (Fig. 3C) in which said connector defines separate leak-free gas and liquid channels between said container and said endoscope, and a second position (Fig. 3D) in which at least one of said channels cannot be made leak-free, thereby preventing displacement of liquid from said container, and

means (25, 30, 31), responsive to disconnection of said single-use means (4-12) from said endoscope, for irreversibly placing said adjustable element in said second position.

15. The connection means of claim 1, further comprising

an insert (24) formed with multiple ramp means (30) on an inner surface thereof, adjacent said piston, for permitting movement of said piston, in response to release of compression of said spring, toward a distal end of said connector, and for subsequently impeding return movement of said piston away from said distal end.

16. The connector means of claim 1, further comprising (Figs. 15A, 15B, 15C)

fork means (65) integrally molded to said piston (21) and having a plurality of prongs having a tendency to spread apart in a relaxed state, said prongs being adapted for retention, in a compressed state in a cylindrical core (83) formed in said hose junction (23), said prongs spreading apart into said relaxed state during transition of said connector to an "after-use" position, thereby preventing re-insertion of said prongs into said core (83) and preventing re-use of said connector.

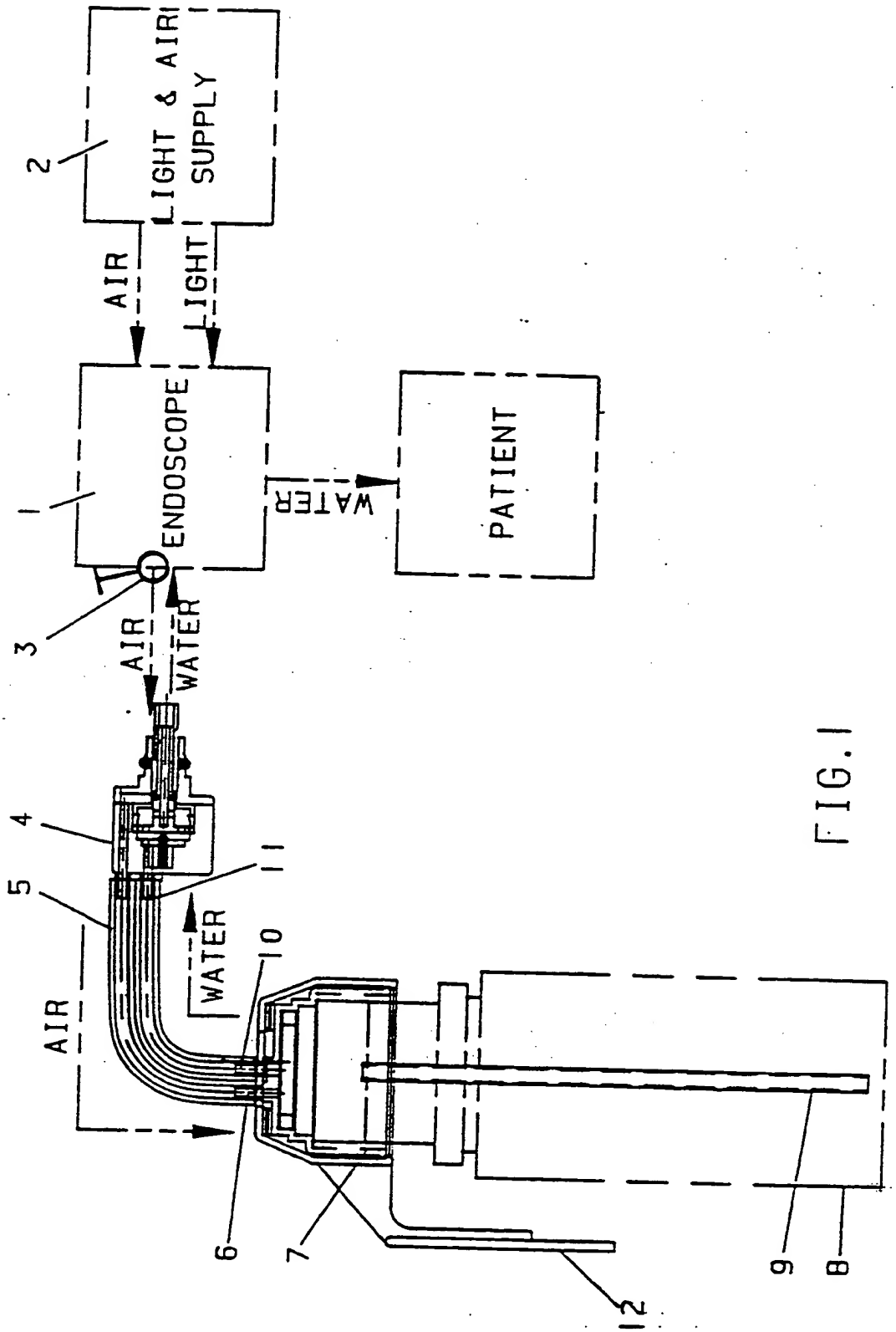

LIGHT & AIR SUPPLY
2
AIR
LIGHT
ENDOSCOPE
1
WATER
PATIENT
3
AIR
WATER
4
5
11
WATER
10
AIR
6
7
9
8
12

FIG. 1

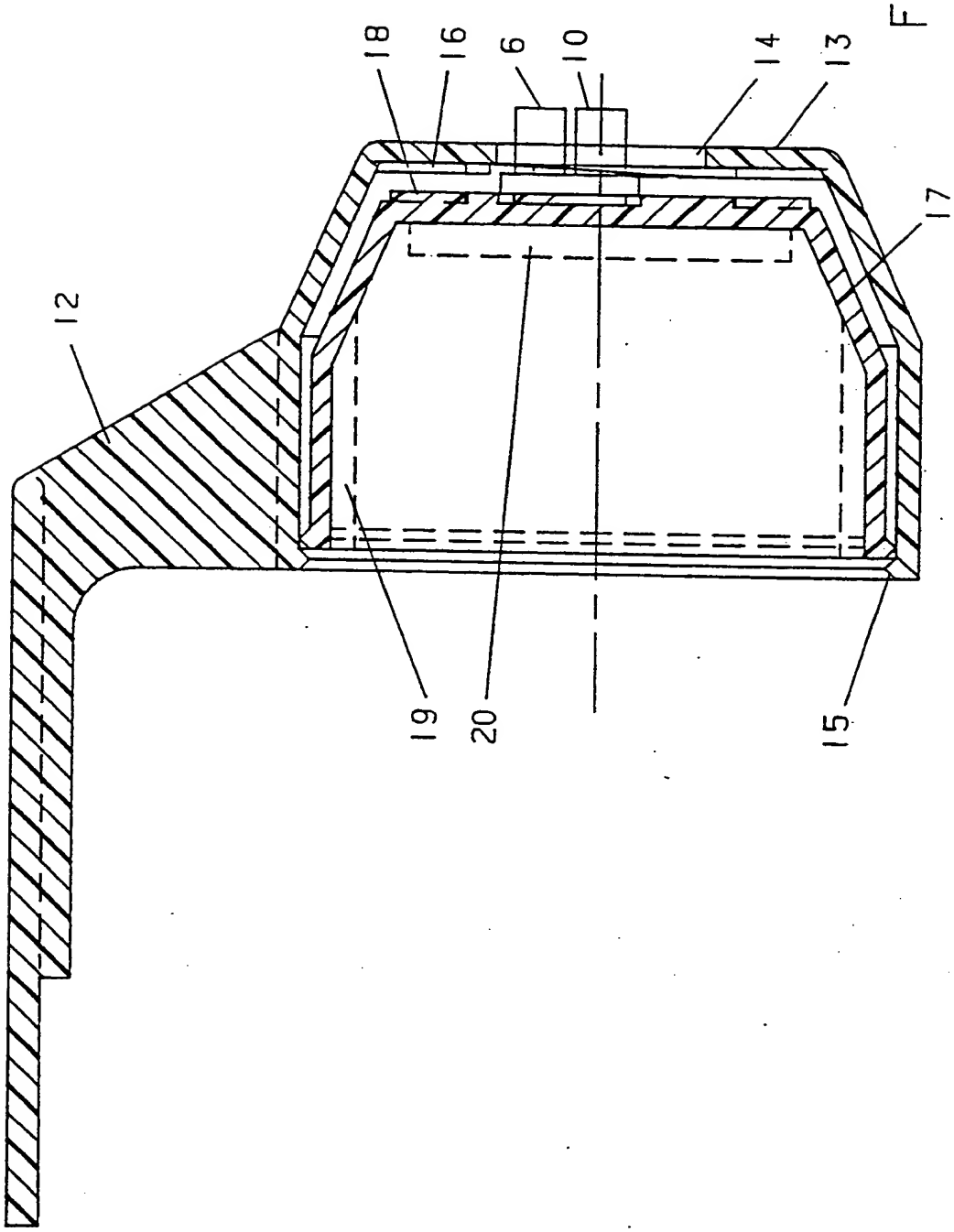


FIG. 2

FIG. 2A

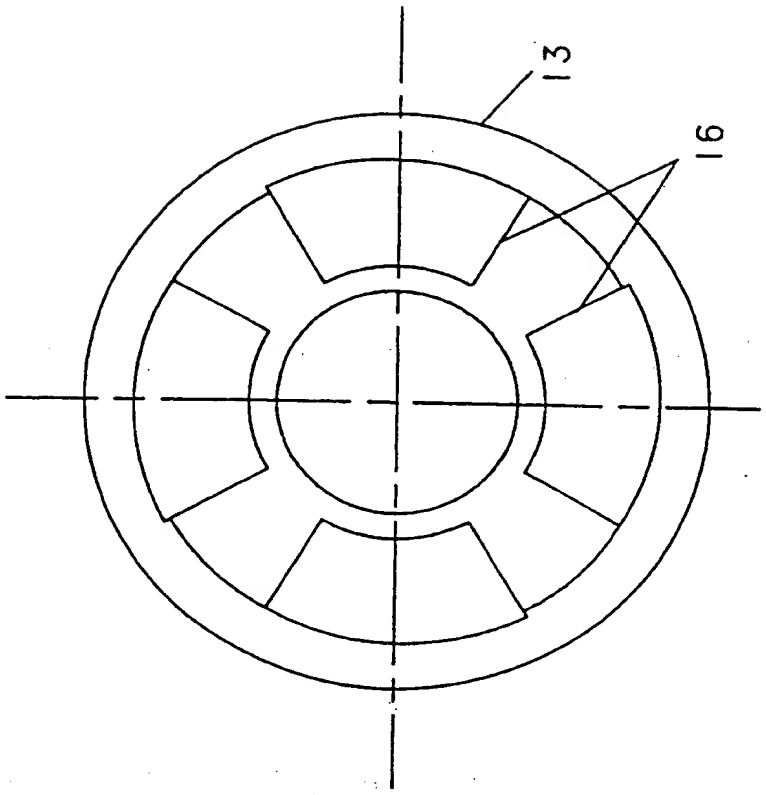
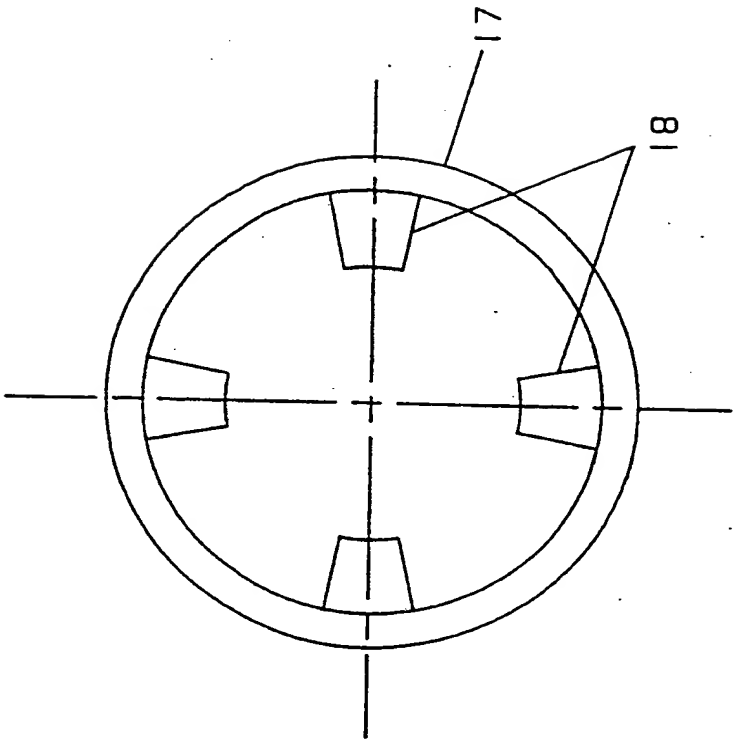


FIG. 2B



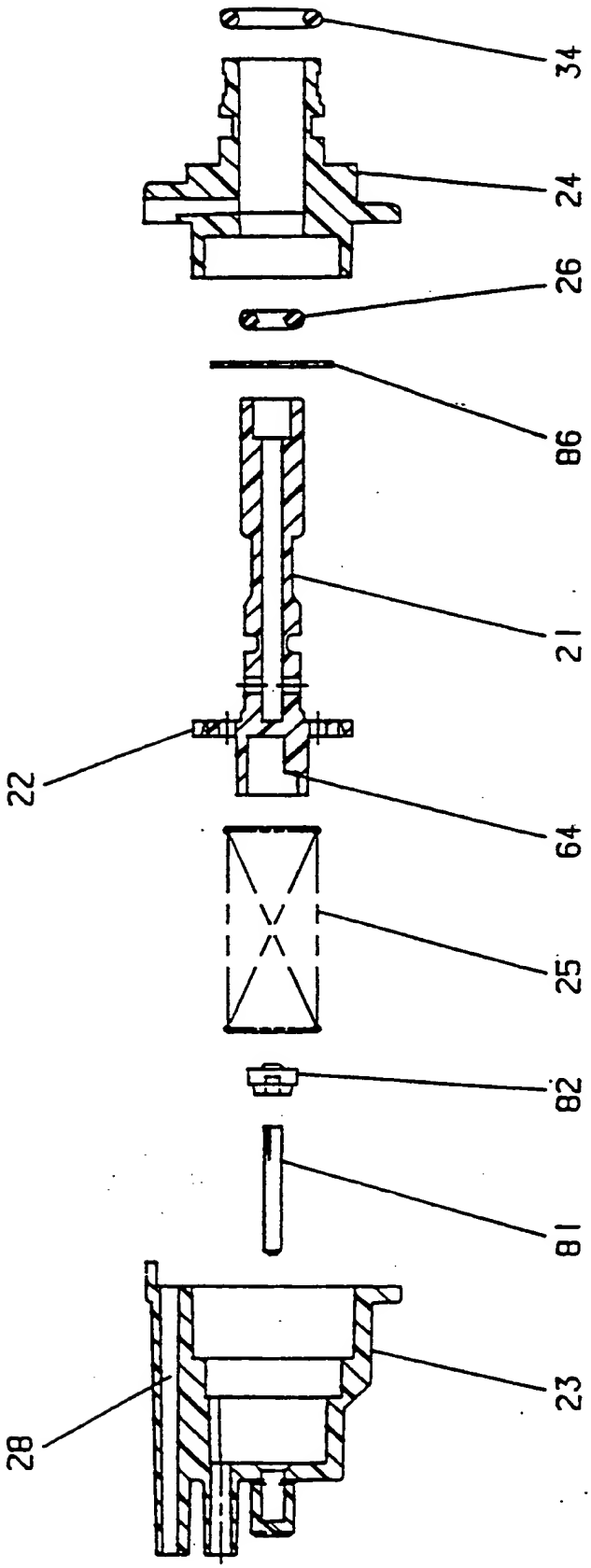


FIG. 3A

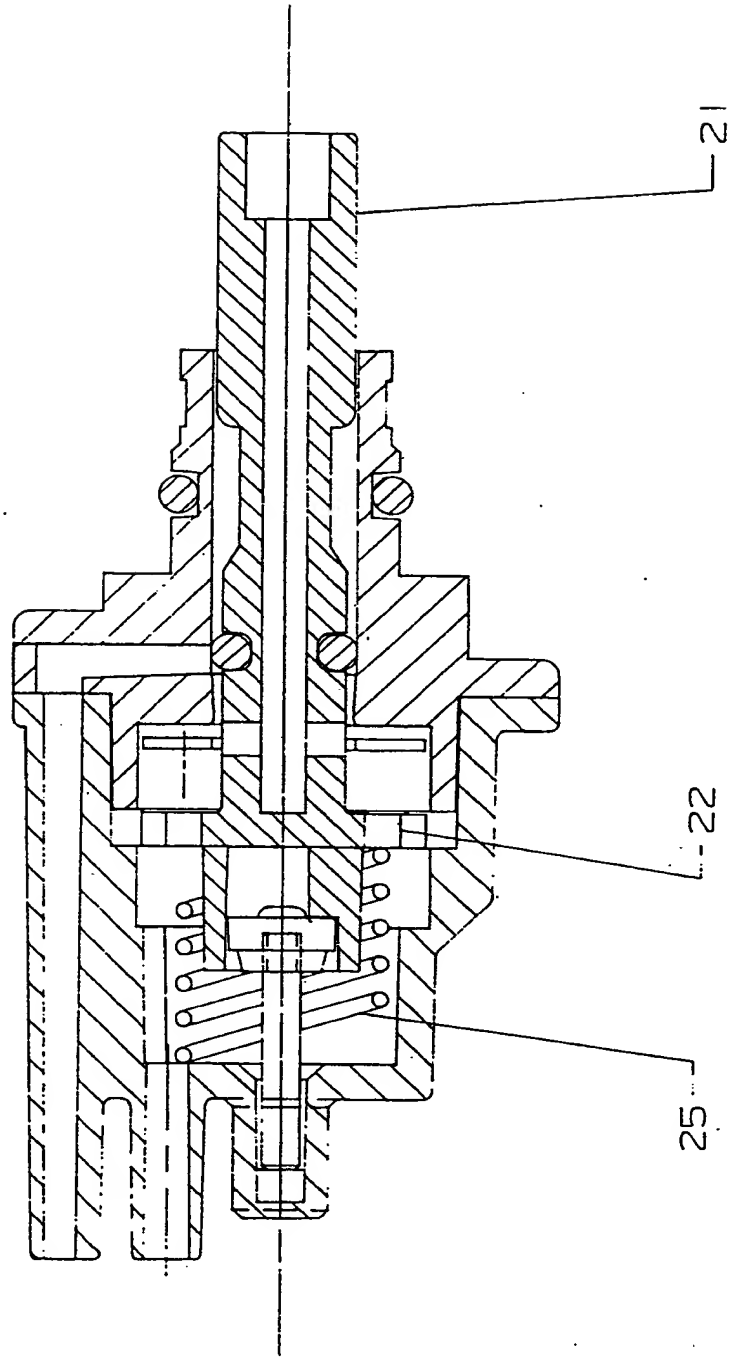


FIG. 3B

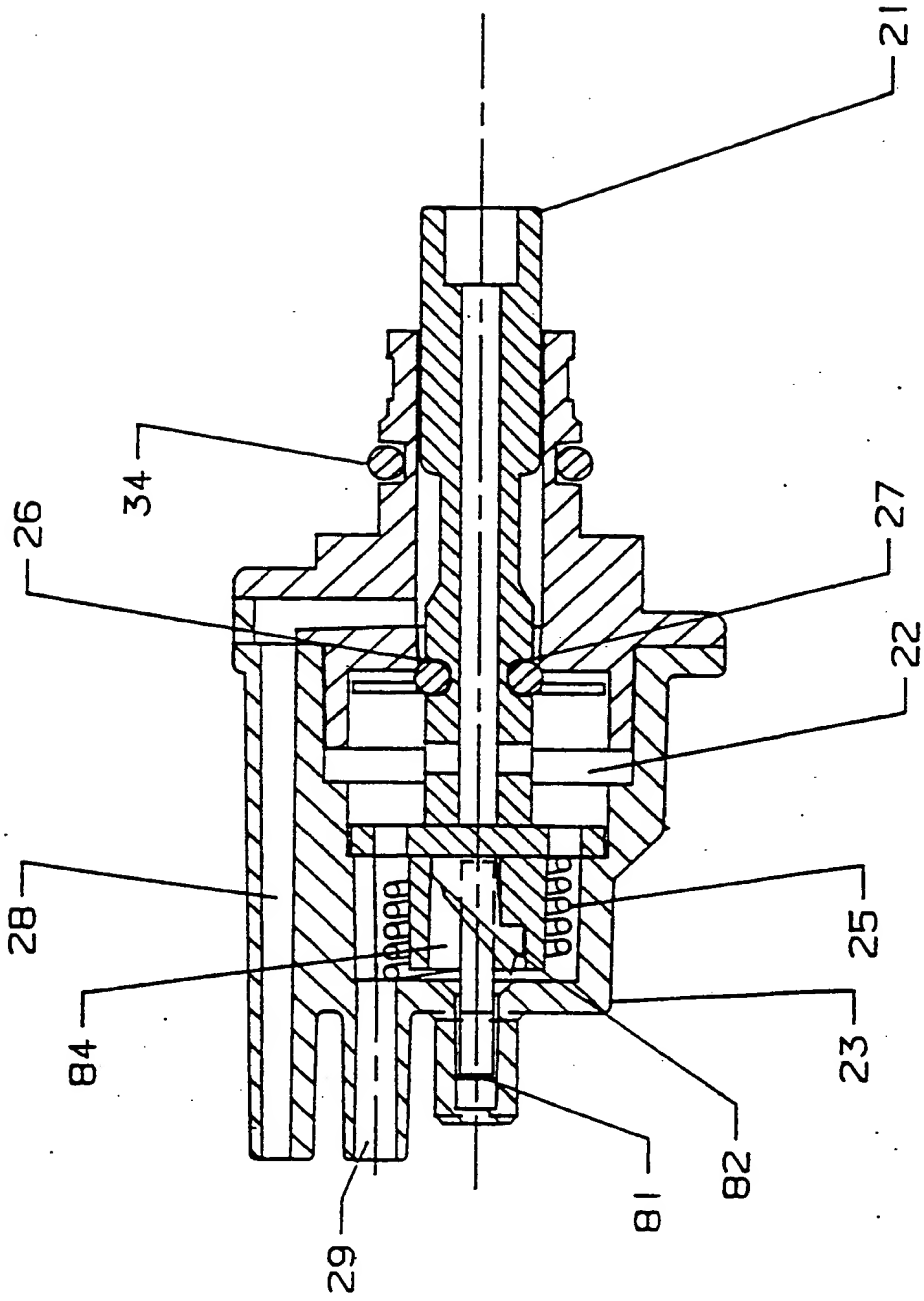


FIG. 3C

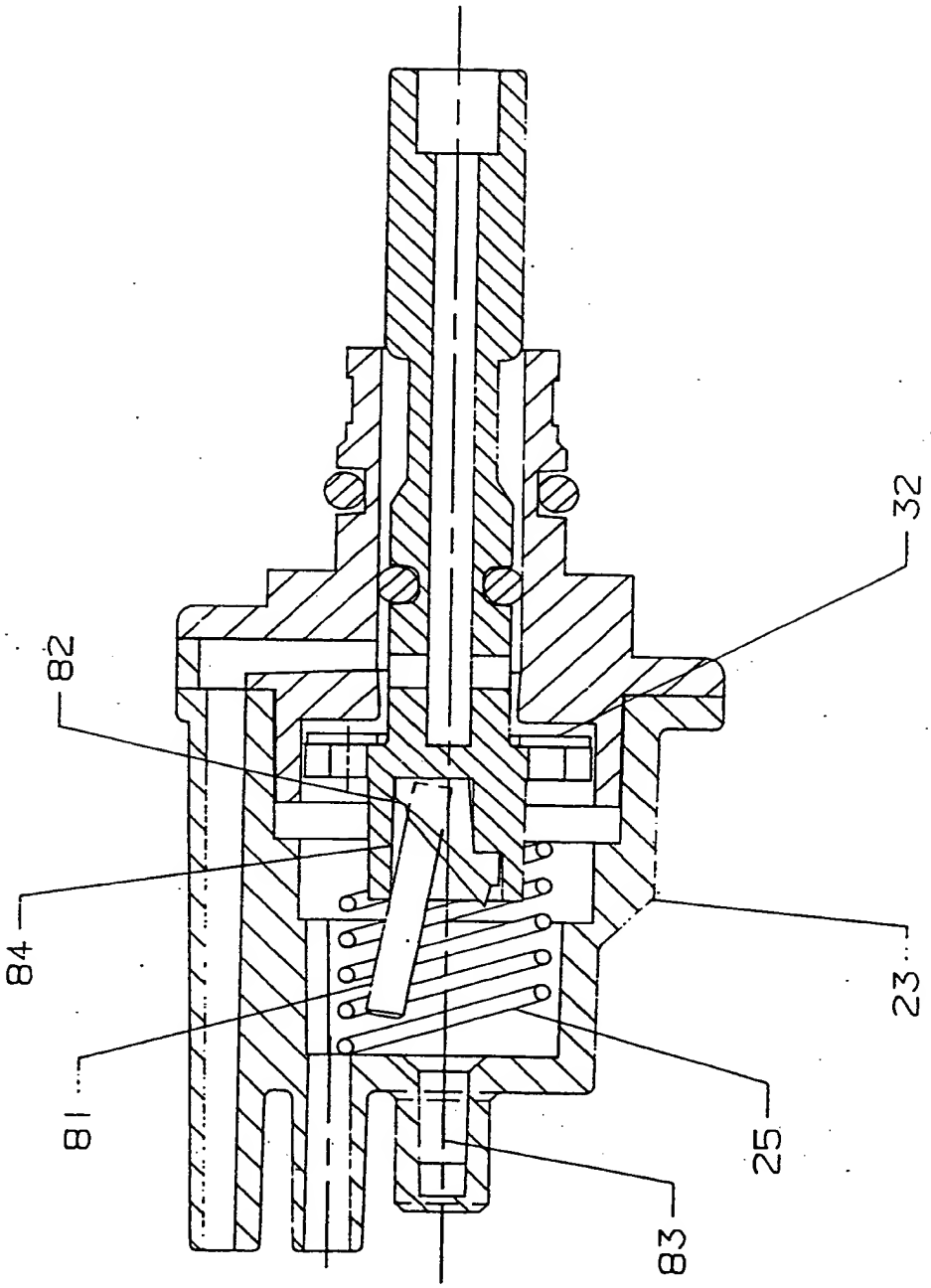


FIG. 3D

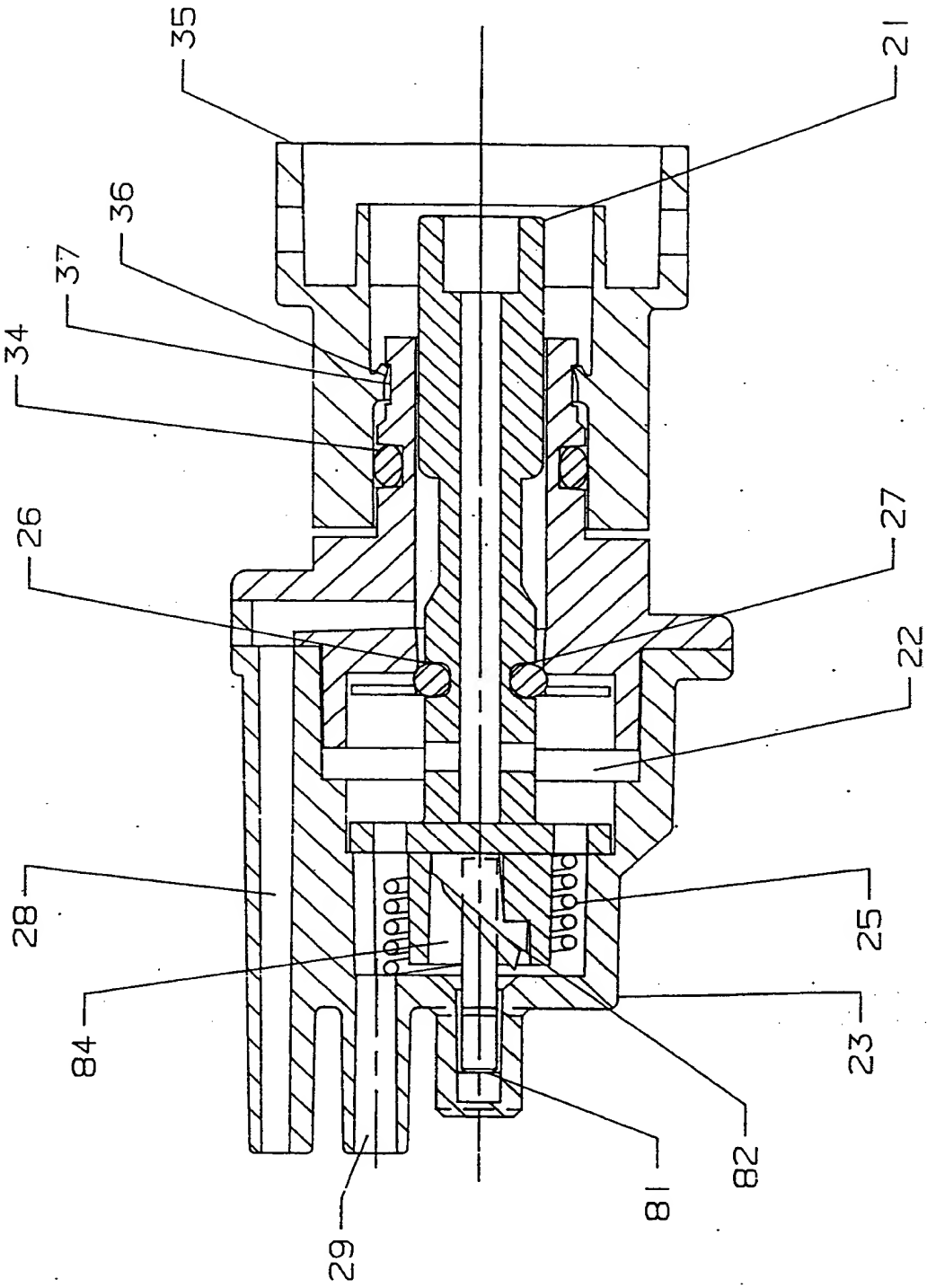


FIG. 4

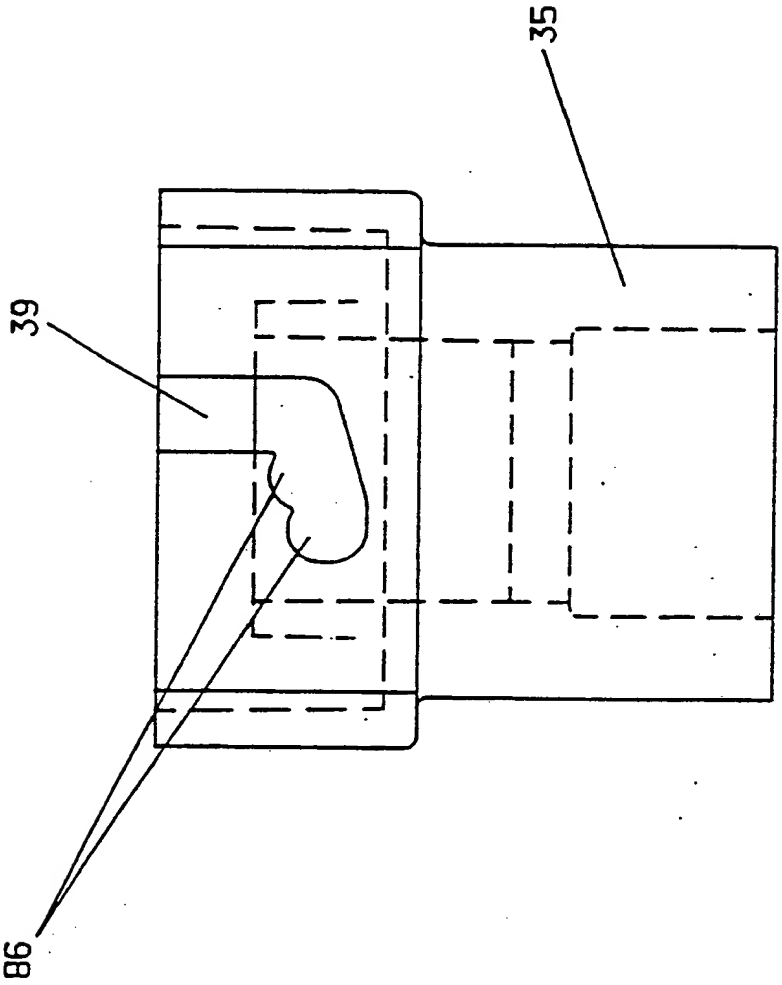


FIG. 4A

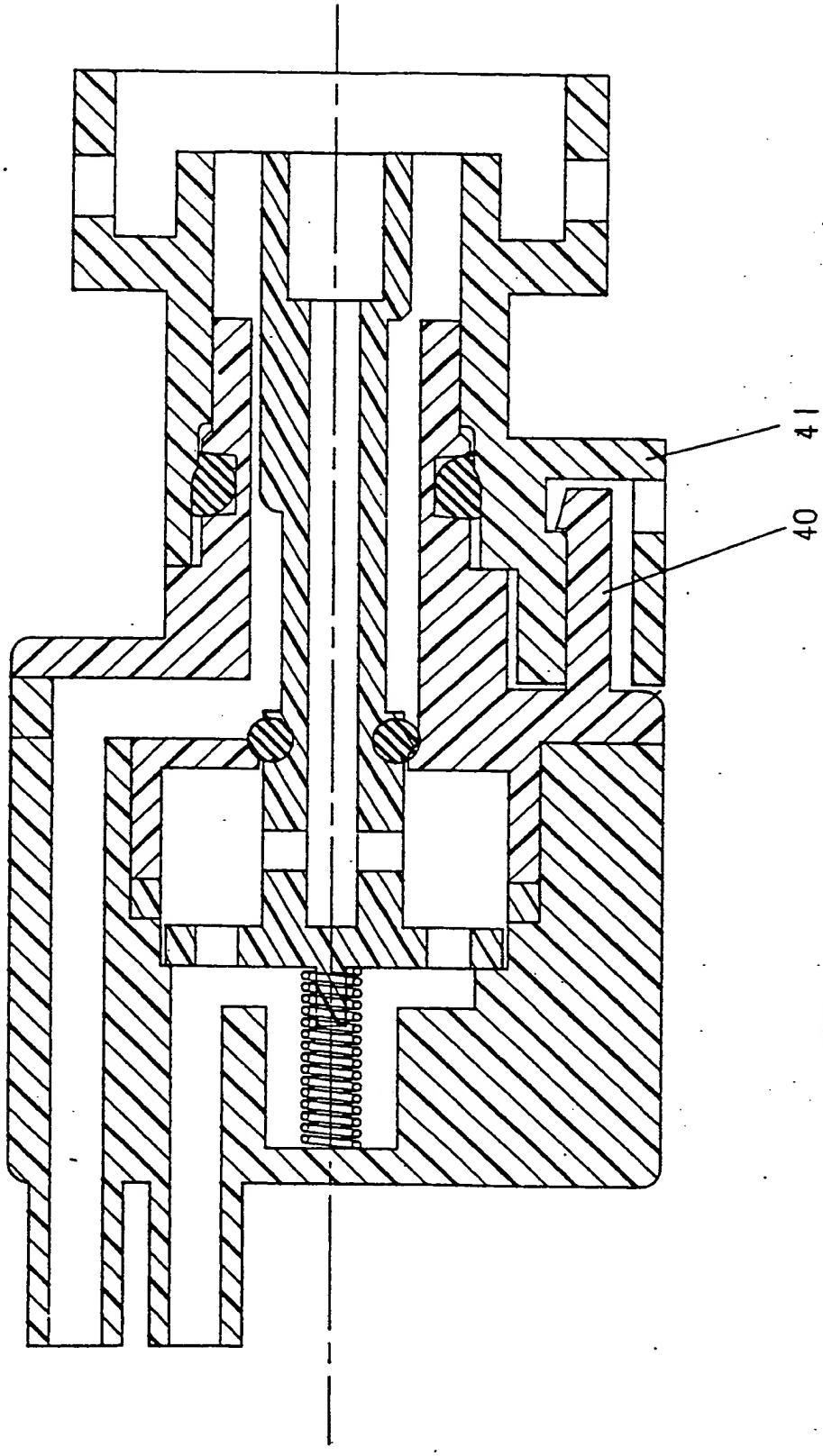


FIG. 5

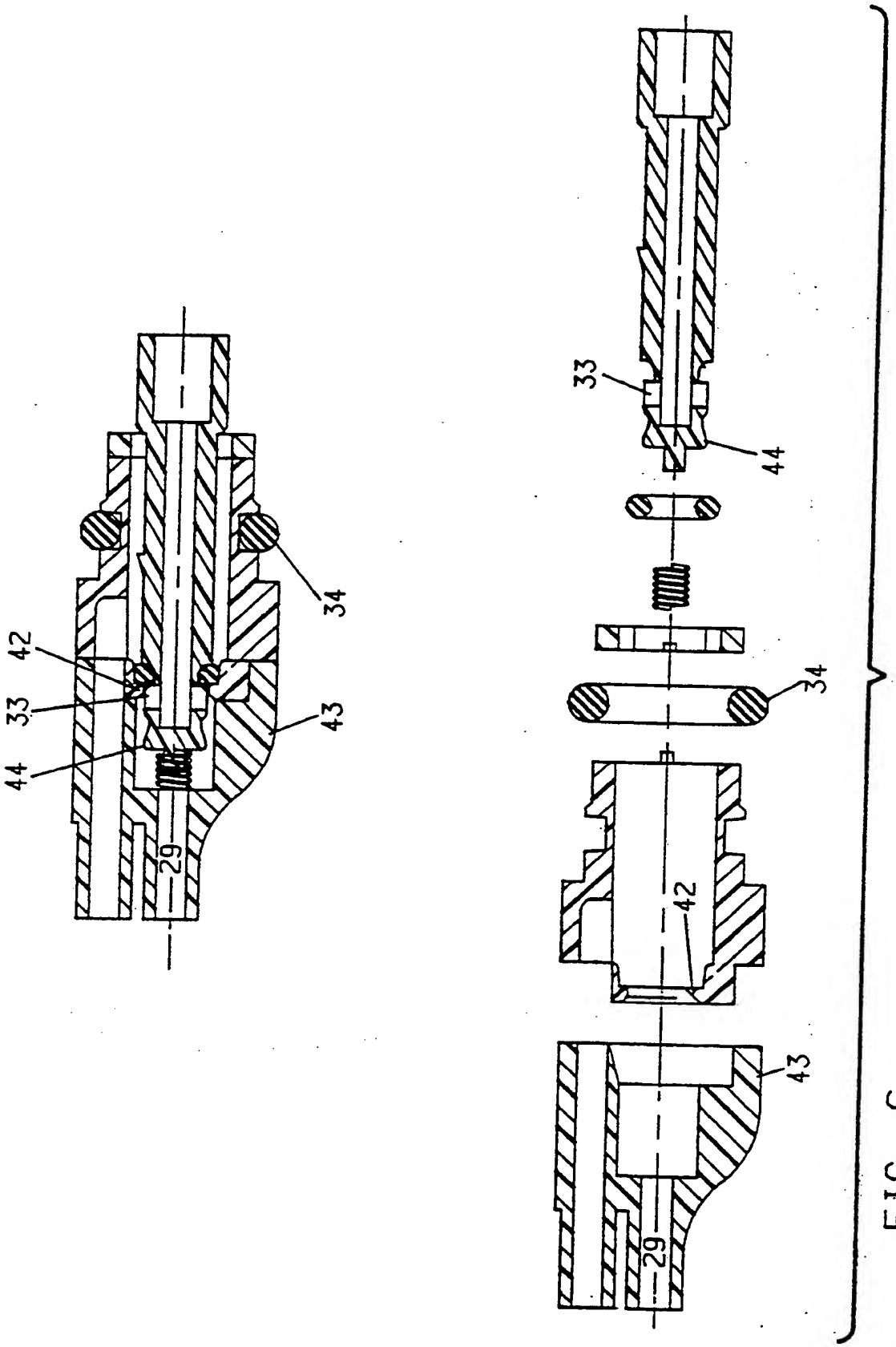


FIG. 6

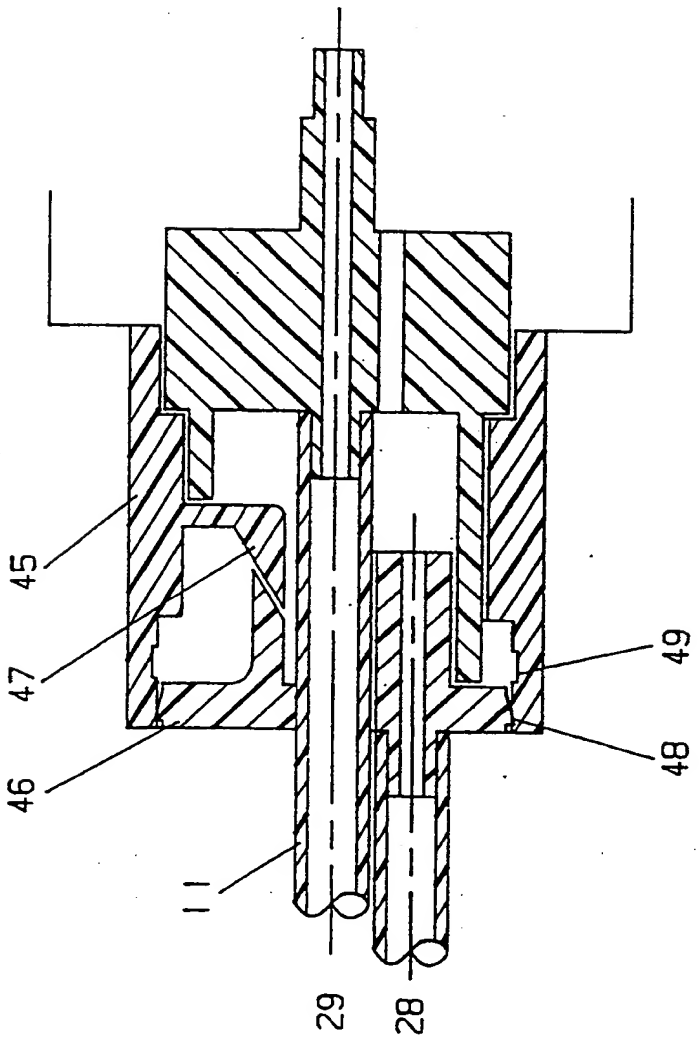


FIG. 7

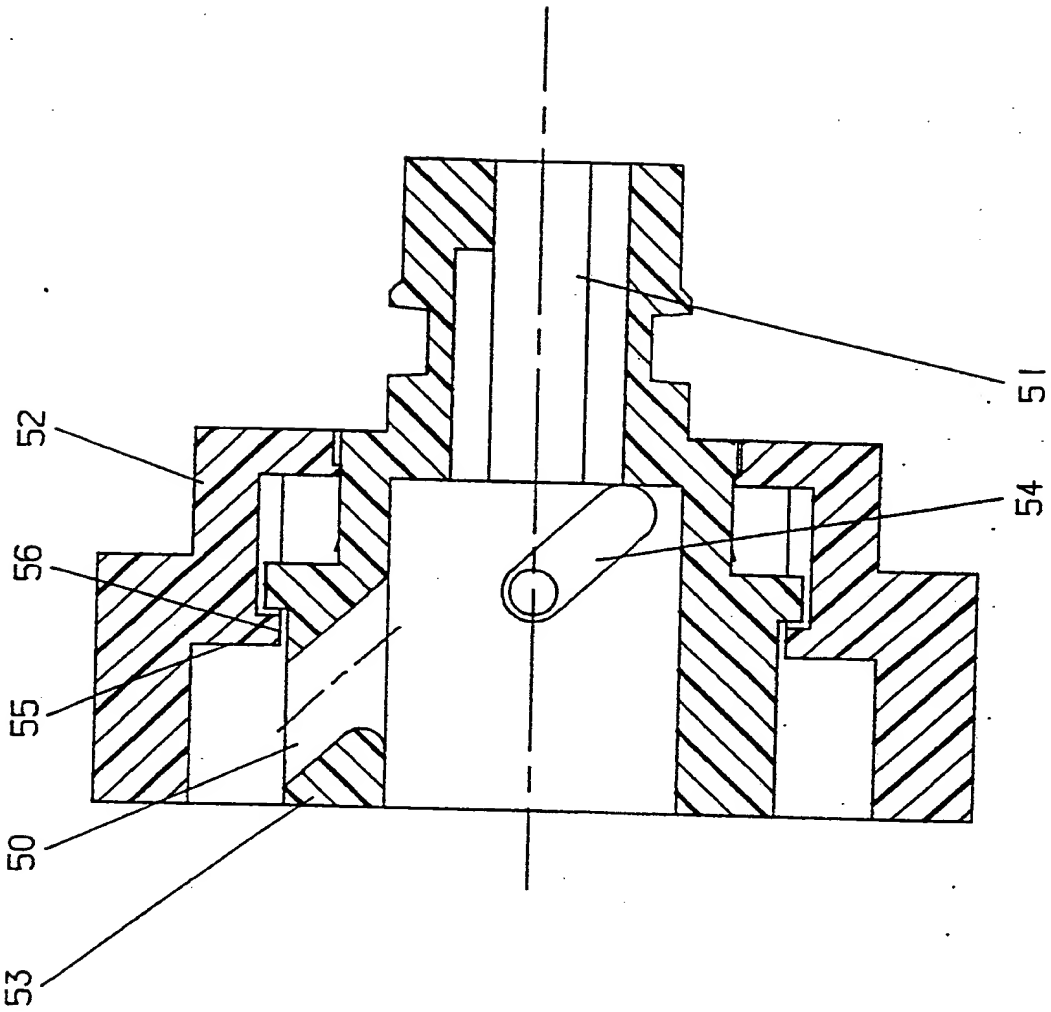


FIG. 8

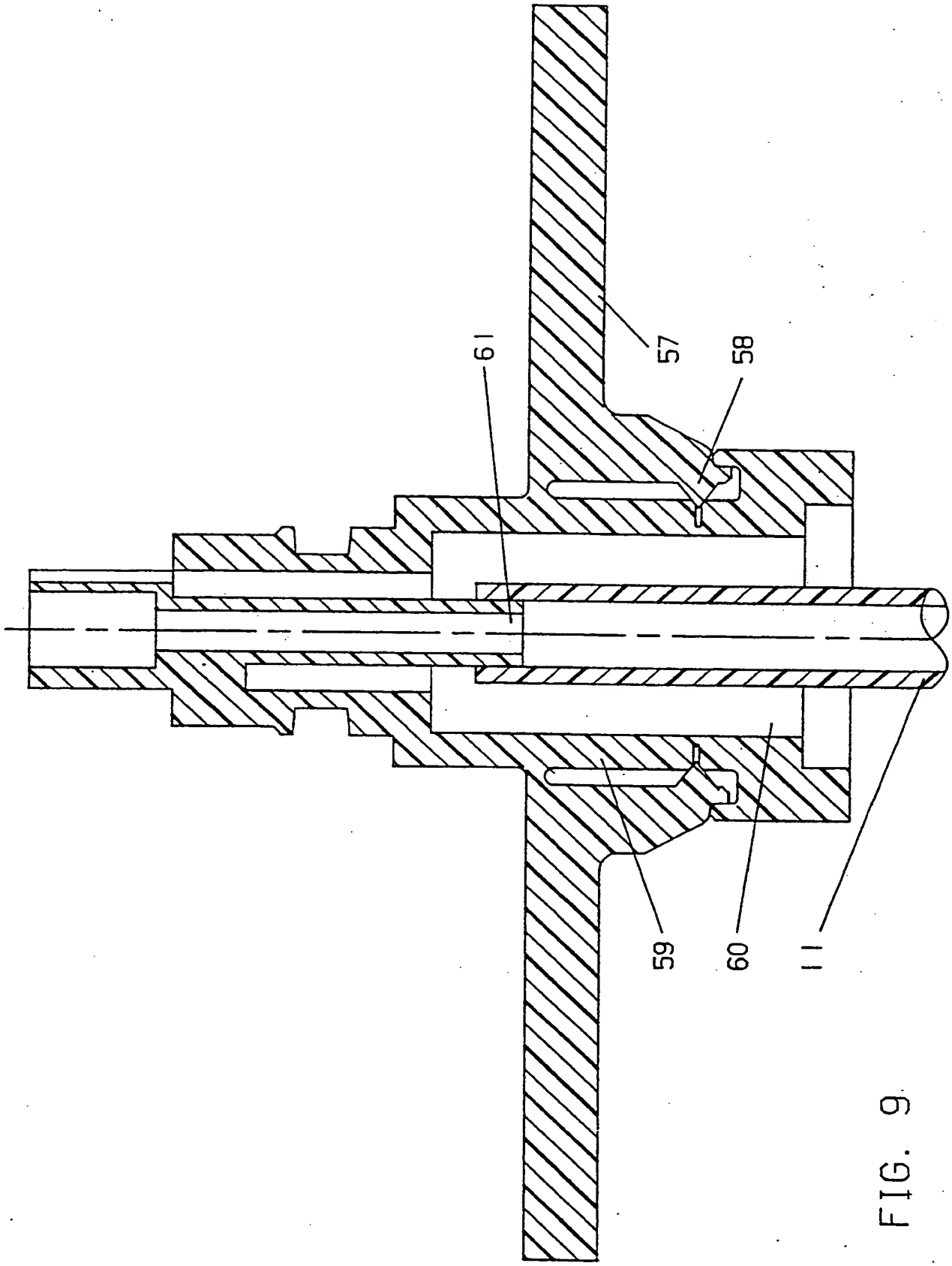


FIG. 9

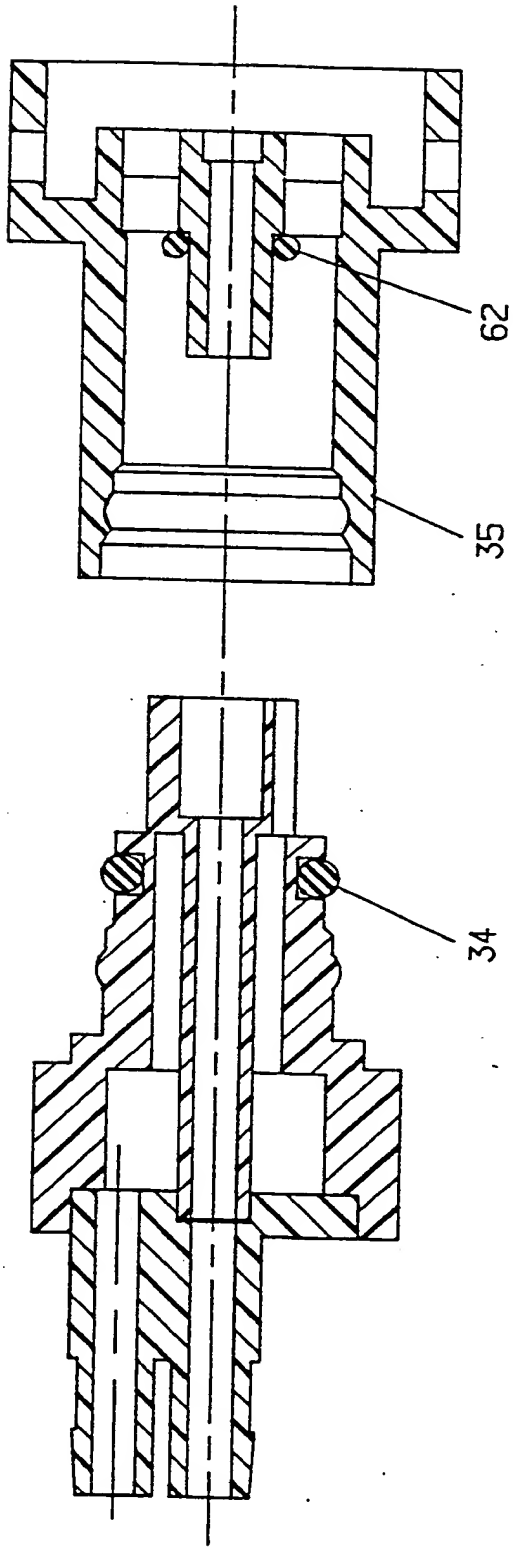


FIG. 10

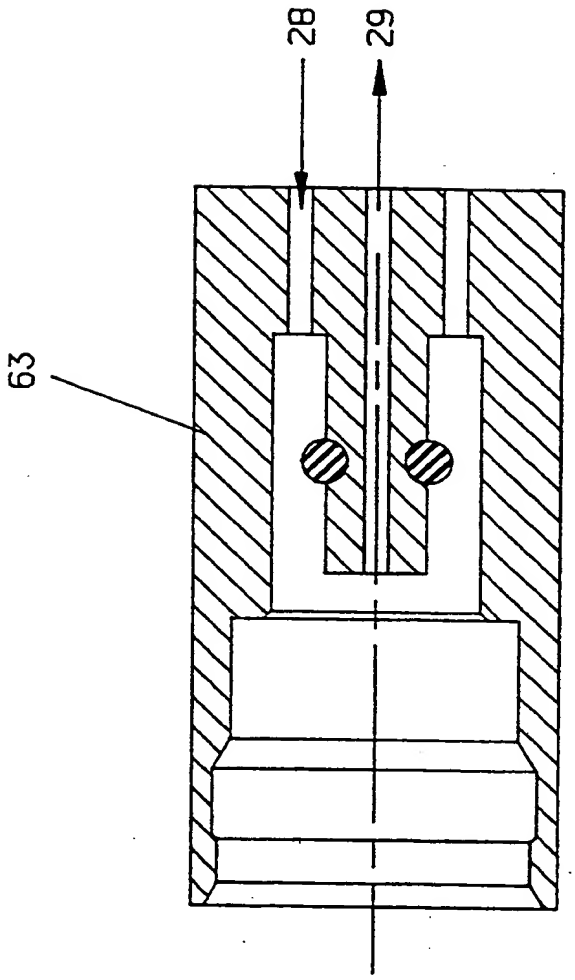


FIG. 11

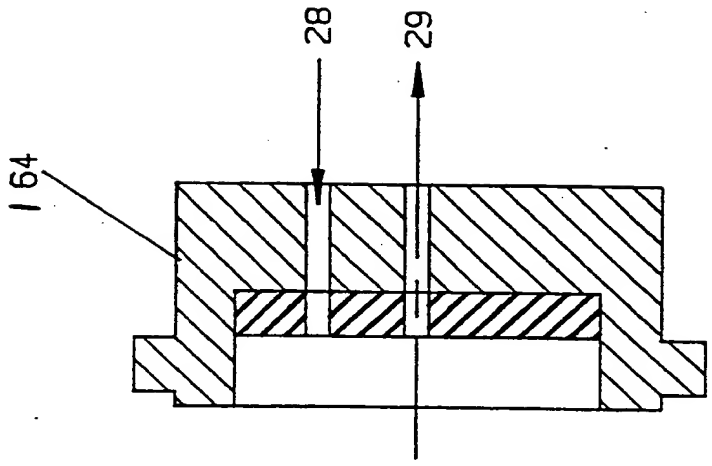


FIG. 12

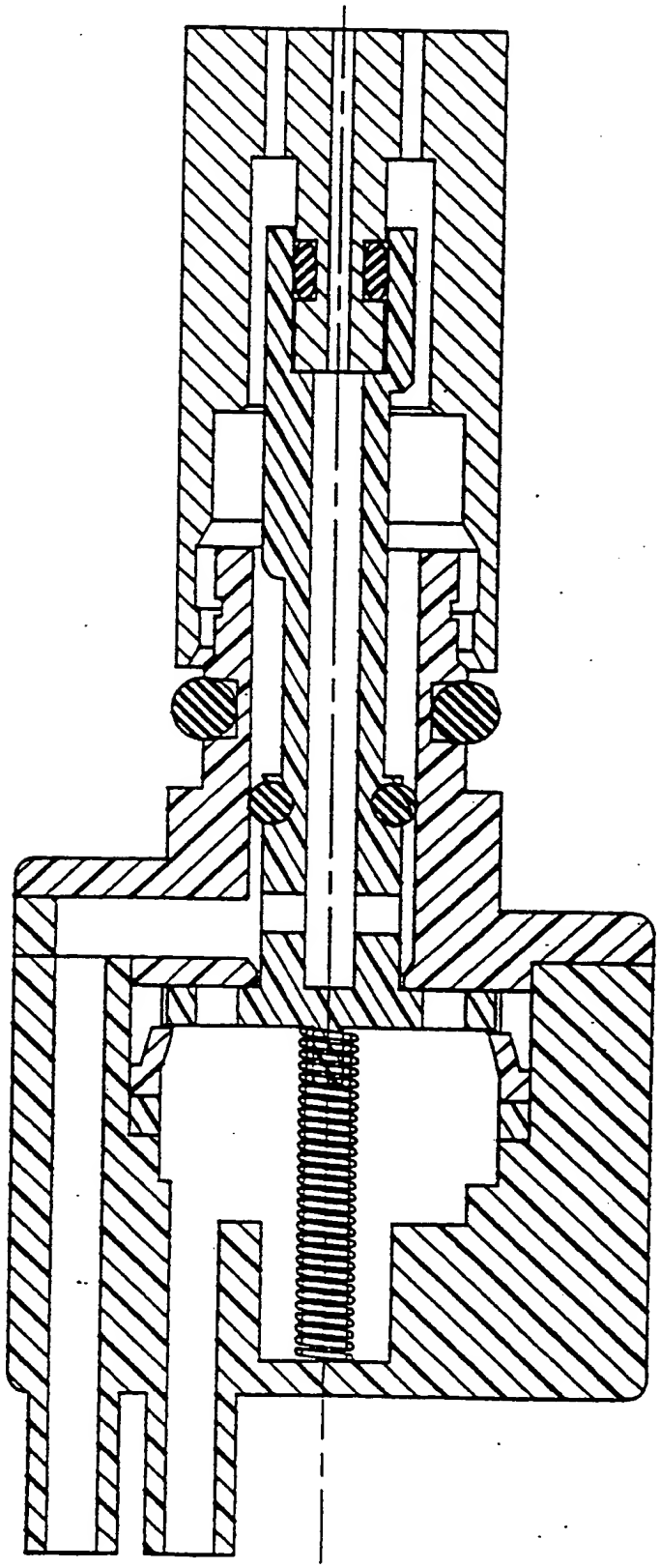


FIG. 13

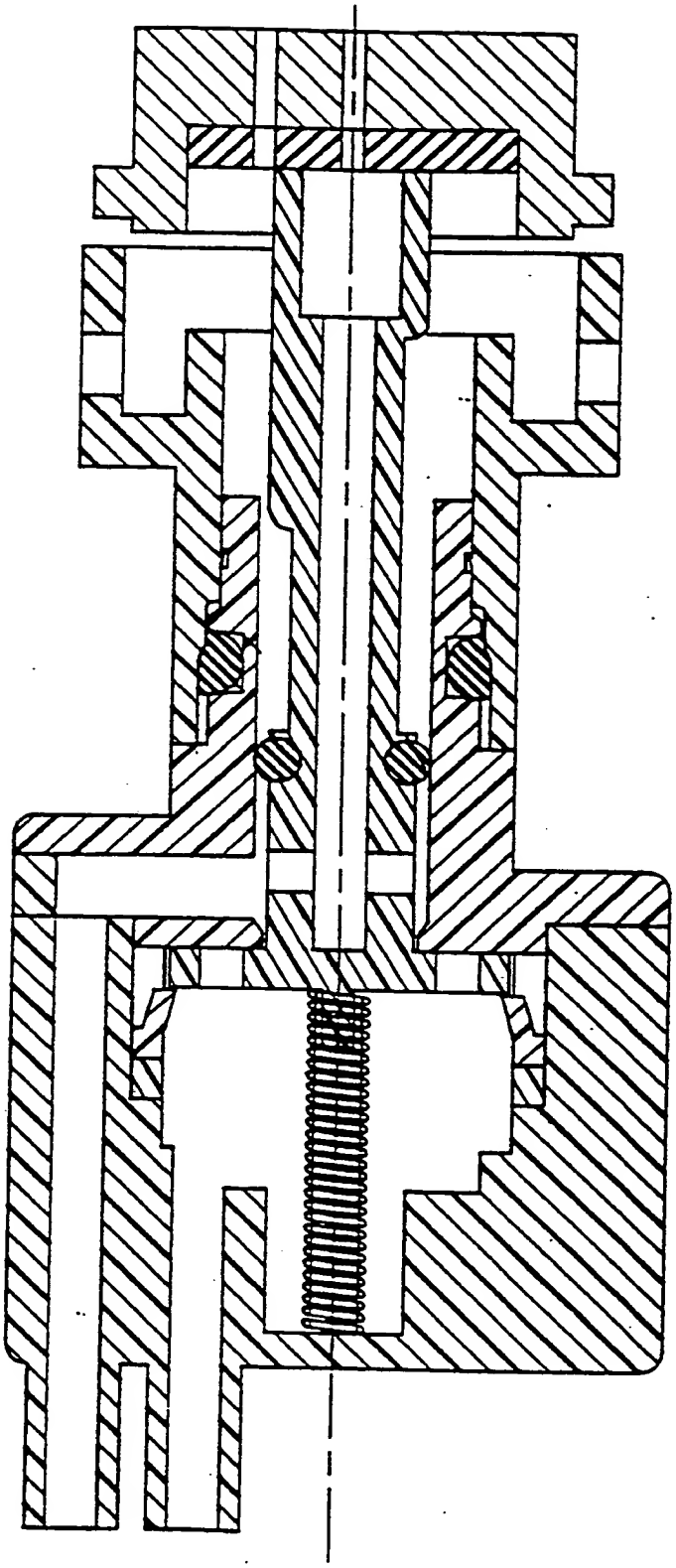


FIG. 14

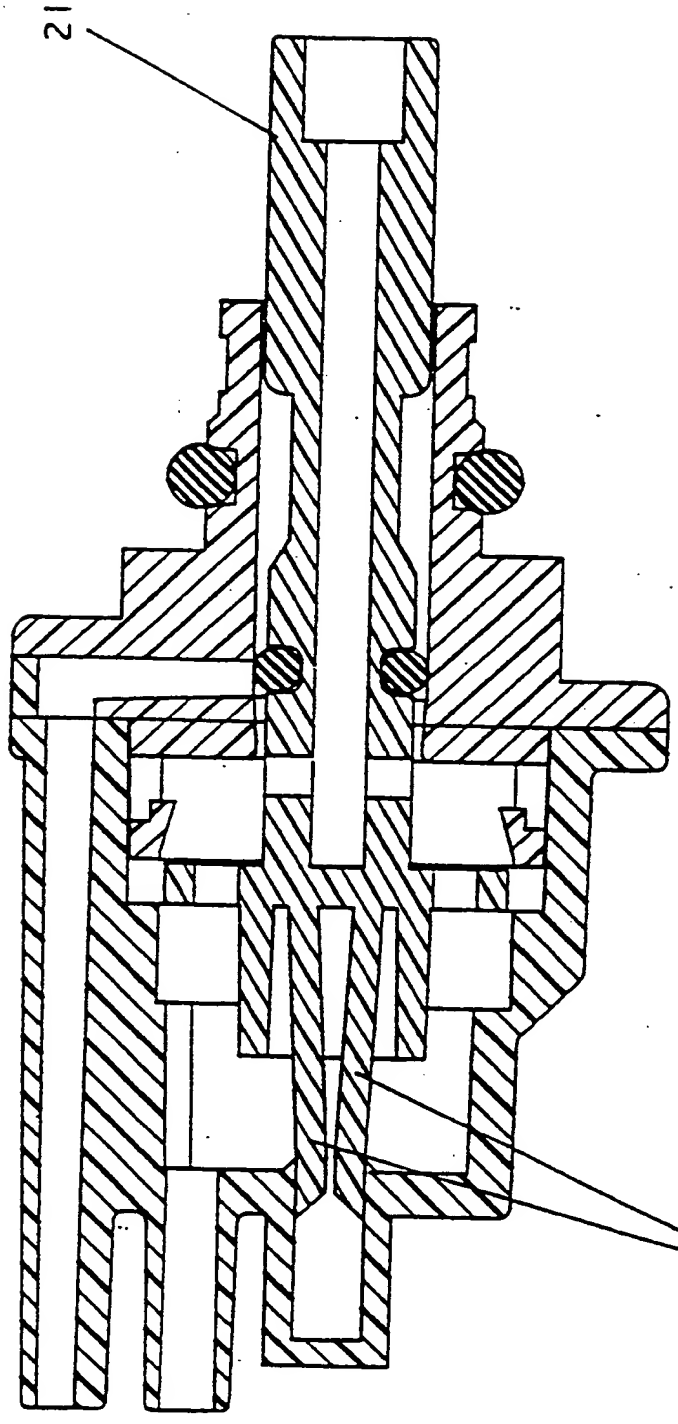


FIG. 15A

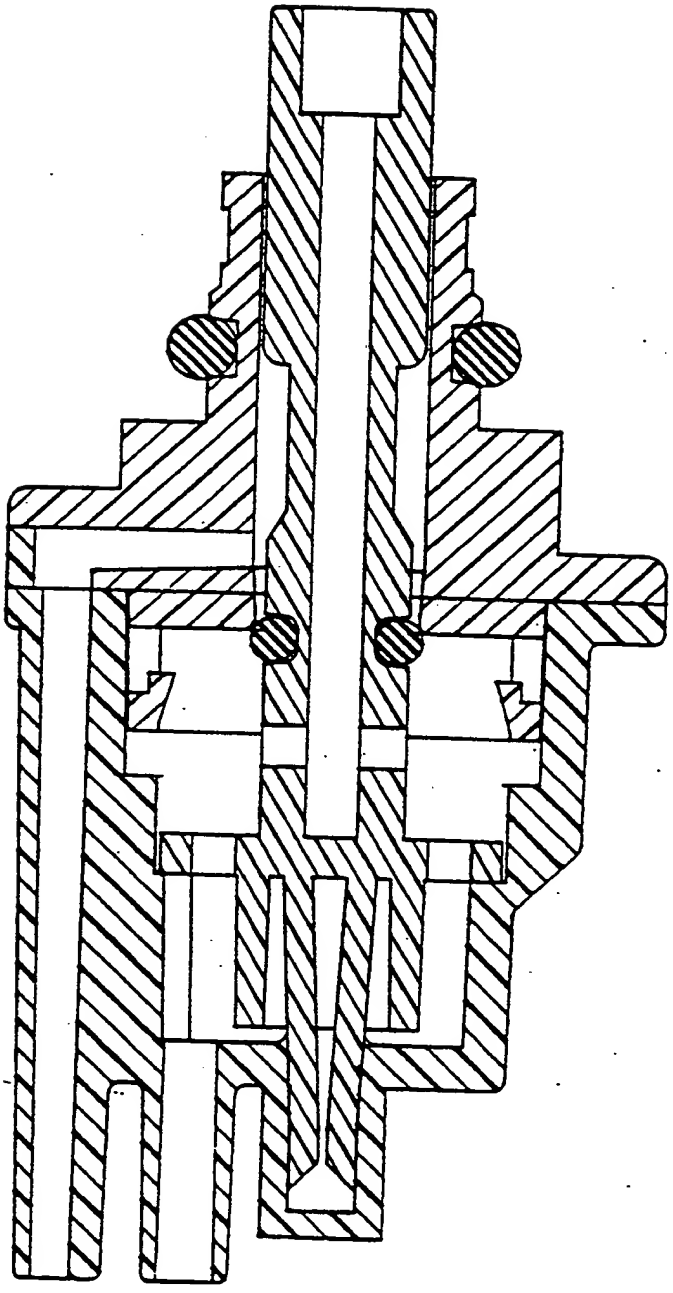


FIG. 15B

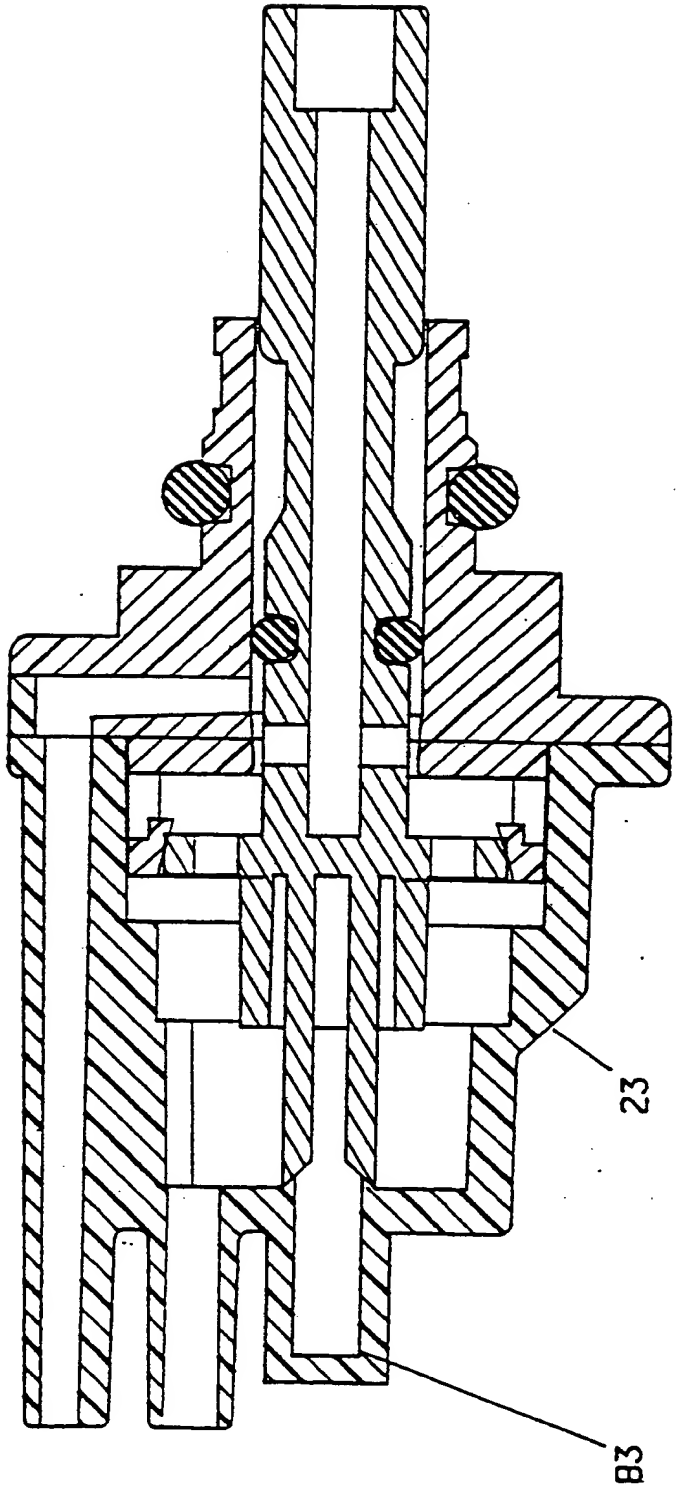


FIG. 15C

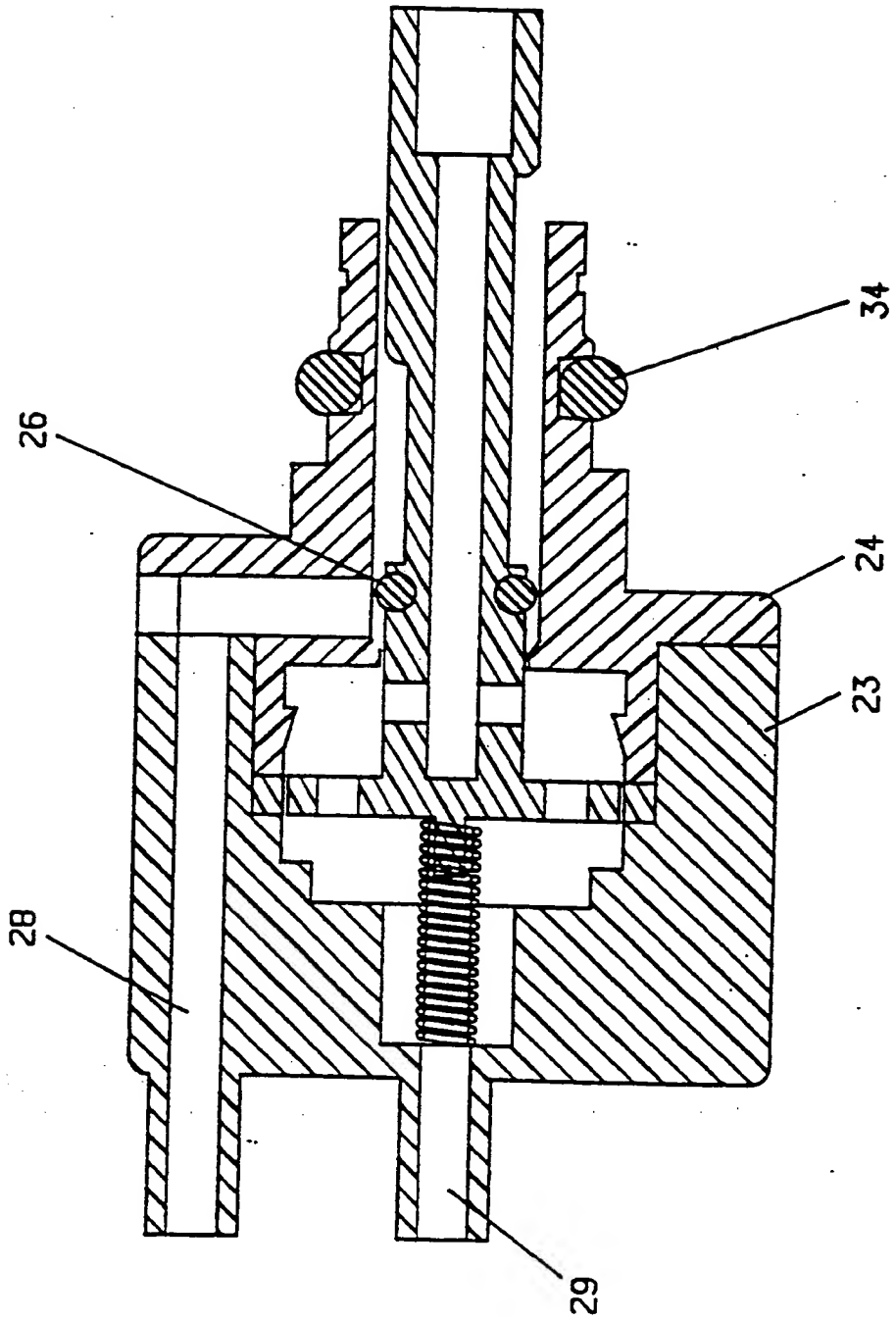


FIG. 16A

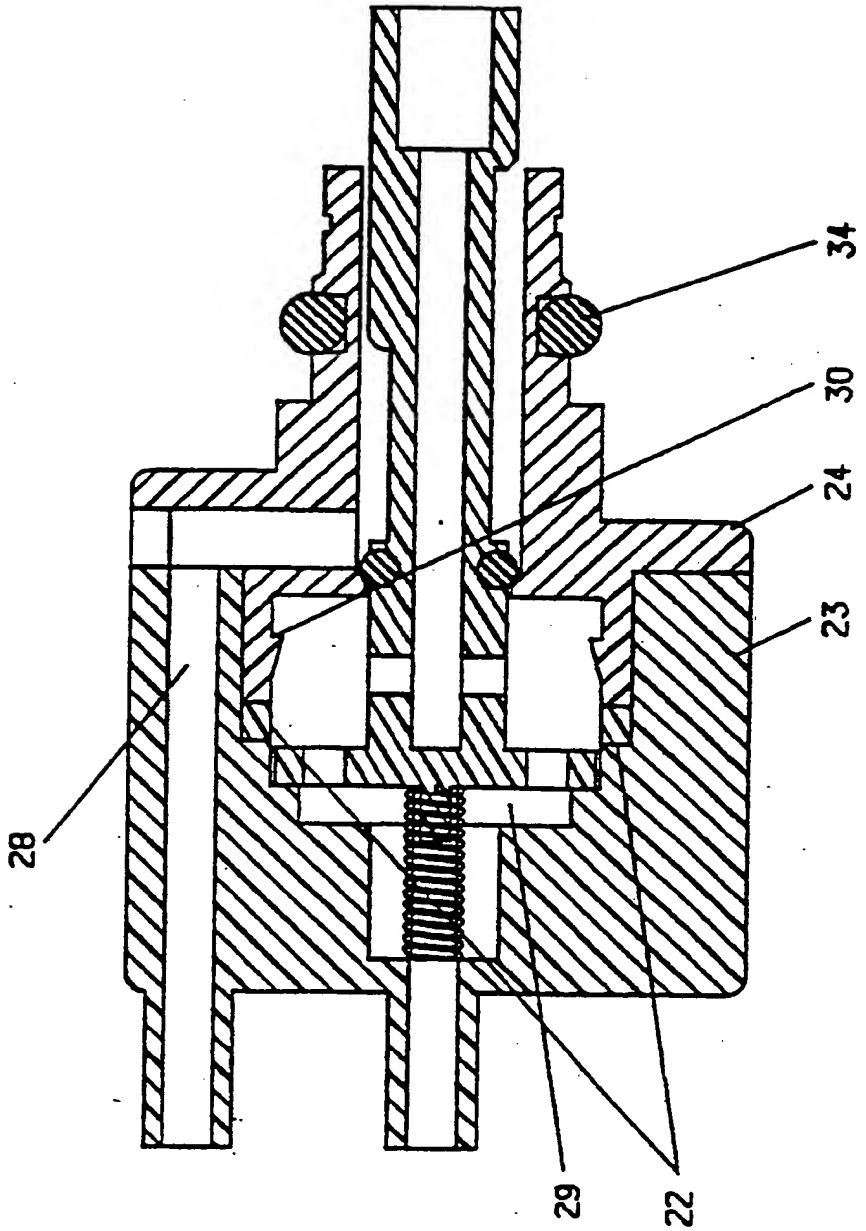


FIG. 16B

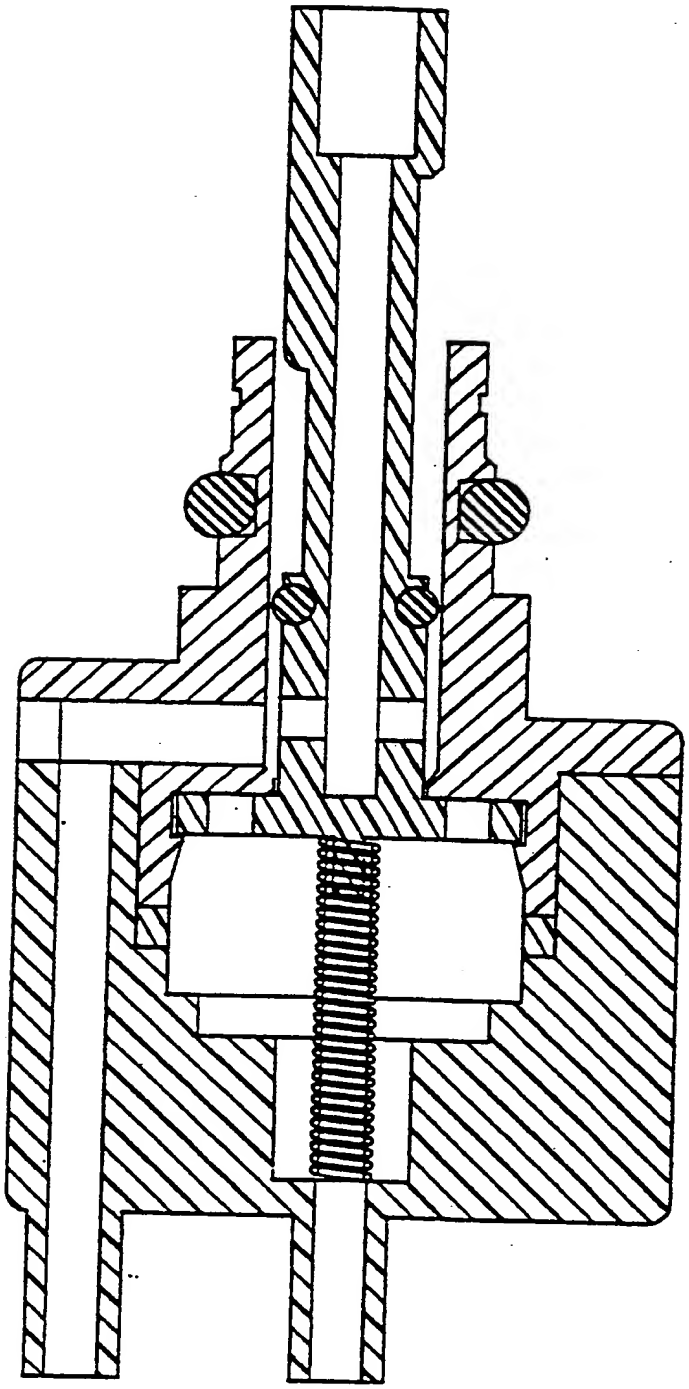


FIG. 16C

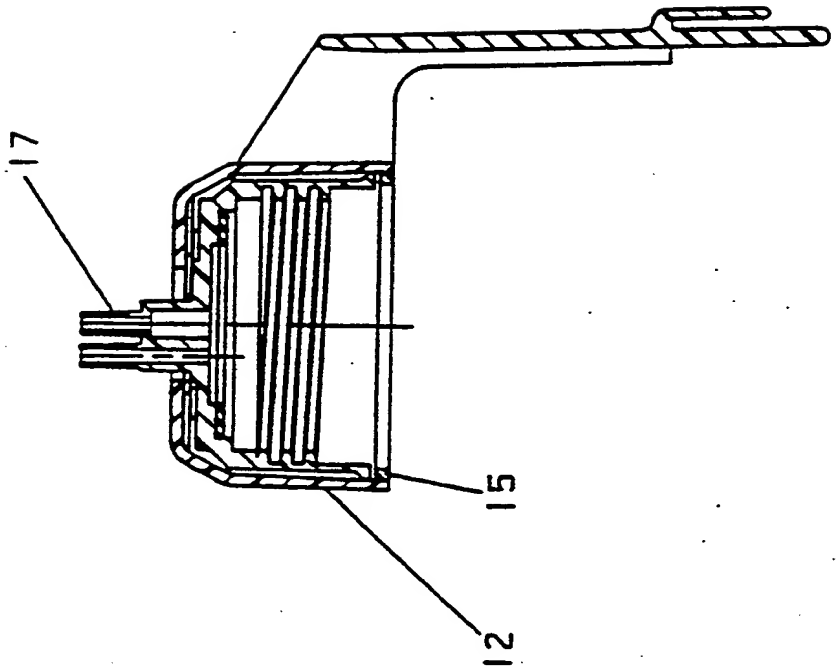


FIG. 17

INTERNATIONAL SEARCH REPORT

International Application No. PCT/US92/00617

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [6]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC(5): A61B 1/00
US. CL.: 128/4

II. FIELDS SEARCHED

Minimum Documentation Searched [7]

Classification System	Classification Symbols
U.S.	128/4,6; 604/110,118; 222/545

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category *	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No. [13]
A	US,A 3,563,258 (HECHLER) 16 FEBRUARY 1991. SEE ENTIRE DOCUMENT.	1
A	US,A 3,640,277 (ADELBERG) 08 FEBRUARY 1972. SEE ENTIRE DOCUMENT.	1
A	US,A 4,193,514 (LANGSTROTH) 18 MARCH 1980. SEE ENTIRE DOCUMENT.	1
A	US,A 4,266,545 (MOSS) 12 MAY 1981. SEE ENTIRE DOCUMENT.	1
A	US,A 4,667,853 (KRUGER) 26 MAY 1987. SEE ENTIRE DOCUMENT.	1
A	US,A 4,709,835 (KRUGER ET AL.) 01 DECEMBER 1987 SEE ENTIRE DOCUMENT.	1
A	US,A 4,860,731 (MATSUURA) 29 AUGUST 1989. SEE ENTIRE DOCUMENT.	1

* Special categories of cited documents: [10]

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
29 JUNE 1992	24 JUL 1992
International Searching Authority	**Signature of Authorized Officer**
ISA/US	JOHN J. WILSON

Form PCT/ISA/210 (second sheet) (Rev.11-87)